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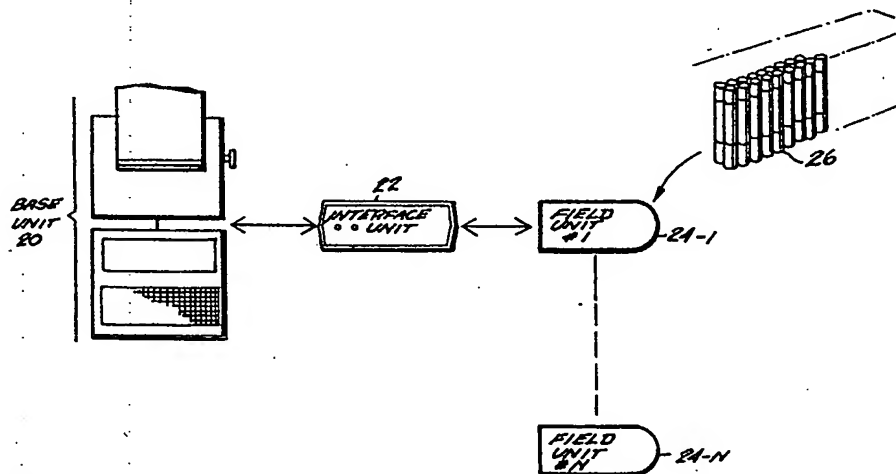
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International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁴ : B65D 83/04	A1	(11) International Publication Number: WO 86/ 06048 (43) International Publication Date: 23 October 1986 (23.10.86)
<p>(21) International Application Number: PCT/US86/00711</p> <p>(22) International Filing Date: 10 April 1986 (10.04.86)</p> <p>(31) Priority Application Number: 722,073</p> <p>(32) Priority Date: 11 April 1985 (11.04.85)</p> <p>(33) Priority Country: US</p> <p>(71)(72) Applicants and Inventors: ATEN, Edward, M. [US/US]; 328 Plantation Road, Bristol, VA 24201 (US). PARKHURST, Larry, E. [US/US]; 1707 Hawthorn Place, Boulder, CO 80302 (US).</p> <p>(74) Agents: PERRY, Glenn, J. et al.; Cushman, Darby & Cushman, 11th Floor, 1615 L Street, N.W., Washington, DC 20036 (US).</p>	<p>(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).</p> <p>Published With international search report.</p>	

(54) Title: CONTROLLED DISPENSING DEVICE



(57) Abstract

The invention relates generally to the art of controlled dispensing and compliance monitoring. Prior art devices relating to medication compliance monitoring lack the necessary control mechanisms to administer complex drug regimens to patients. The present invention overcomes the deficiencies by providing a controllable dispensing device for use by a drug therapist for the unsupervised administration to a patient of a drug therapy regimen. A field unit (24) is loaded with a plurality of medication containers (52) in a predetermined sequence. Along with the medication, a program of dosing times is stored in electronic memory (102) of the field unit. This program is defined using a computerized base unit (20) and is transferred to the field unit via an interface (22) between the base and the field units. The field unit includes a display (204) and alarm (208) for alerting the patient as to the times for dispensing and administering the medications in the containers. The field unit permits dispensing of containers only in accordance with the predefined dispensing. Later, the field unit can be debriefed by the base unit via the interface and the base unit prepares a report of medication compliance for the drug therapist.

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CONTROLLED DISPENSING DEVICEBACKGROUND OF THE INVENTIONField Of The Invention

5 This invention relates generally to the art of controlled dispensing and compliance monitoring. It has particular application to the art of unsupervised drug dispensing to a patient although the principles of the invention apply to controllable dispensers of any types of material.

10 The presently preferred embodiment of the invention provides a controlled medication dispenser. The dispenser can be preprogrammed by a drug therapist using a base unit (specially programmed computer) to which the dispenser is temporarily coupled, to

15 permit a patient access to drugs stored in a portable field unit only in accordance with predetermined criteria, such as for example at particular times. A digital display on the dispenser specifies the next dosing time and will

20 instruct the patient on proper make-up doses in the event of missed doses. The portable field unit records actual times of medication dispensing and can easily be debriefed by the base unit (computer) which then prepares a medication compliance report

25 for the drug therapist.

Background Of The Invention

"Controlled dispensing" refers to the concept of permitting a user to dispense some item according to a predetermined schedule or set of rules, rather than permitting unrestrained access.

30 A significant application of the art of controlled dispensing relates to drug dispensing.

"Compliance monitoring" refers to the concept of recording a user's actual dispensing activity compared to a previously prescribed regimen. A significant application to the art of compliance monitoring also relates to drug therapy.

5 As drug research and therapy become more and more sophisticated, drug researchers and therapists have an increasing need to administer complex drug regimens to patients; to restrict access to medications in some instances; and to
10 evaluate the patients' compliance with those drug regimens.

 The most accurate way of administering a drug regimen and measuring compliance of a patient or test subject is direct supervision of each dose
15 of medication. The manpower required for this type of drug administration is extraordinary and usually requires hospitalization. The alternative of prescribing a drug regimen and leaving it completely to the patient to follow and report back usually
20 results in poor compliance and inaccurate reports.

 Controlled drug dispensers and compliance monitoring equipment provide a middle ground between direct supervision and no supervision so that relatively dangerous drugs can be administered
25 without direct supervision and clinical drug studies can be carried out with relatively high reliability.

 As the U.S. Department of Commerce National Technical Information Service Publication PB-278 973 entitled "Possible Designs of Medication Monitors",
30 prepared at the National Jewish Hospital and Research Center, Denver, Colorado, for the American Lung Association (April 1978) points out, the genesis of the medication compliance monitor goes back to May 1962. This early concept was for a

medication monitor utilizing radioactive material and photographic film to determine when patients removed medication from a medication dispenser.

Since then there have been several publications on different devices utilizing the same principle, as well as field trials. Since the original publication, the interest in the field of patient compliance with drug regimens grew enormously.

"The Unrealized Potential of The Medication Compliance Monitor" was discussed by Thomas S. Moulding, M.D., at the National Jewish Hospital in a February, 1979 commentary appearing in Volume 25, November 2, of Clinical Pharmacology and Therapeutics. That commentary provides some insight to the historical development of the art of medication compliance monitoring. This Moulding commentary discusses an early version of a radiographic-type compliance monitor. As medication compliance monitoring further developed, various arrangements appeared in the literature and marketplace. Moulding describes a radiographic compliance monitor capable of showing dosing patterns. Each container holds a full daily dose of medication. However there is not provided any alerting features to help the patient to remember to take dosages. Processing and interpreting the compliance record are awkward. Potential hazards are associated with the use of a radioactive source. No control mechanisms are used -- Access is not controlled nor is the number of dosages taken at one time.

Moulding anticipates the use of strip packaging and microprocessors for improving compliance monitors' design but no practical details

are given on how to accomplish these design improvements. It does not appreciate the utility of a device capable of delivering multiple medications in complex regimen. The commentary does not teach how to build a reliable and tamper-proof dispensing mechanism; a successful strategy for field, interface, and base unit electronics and software is not given.

Lederle Laboratories (American Cyanamid Company) developed a digital module for the cap of a medicine bottle for reminding the patient when he last took his medication. This "reminder" cap was intended to help people to take medication at the proper time. However, such an arrangement has certain fundamental inadequacies: The clock does not indicate when the next dosage is due. The patient must still remember the proper dosage schedule. There is no alarm to get the patient's attention when the next dosage is due. The cap has no memory to show the therapist when dosages were taken. There is no control over when the bottle cap is opened or the number of dosages taken after the cap is removed. Also, multiple caps are needed for multiple drug therapies; and the patient is not guided as to how much of each drug is to be taken.

A "Med Tymer" medicine bottle cap was developed by Boston Medical Research, Inc. It includes preprogrammed light and sound alarms that announce when the next dosage is due. 1/day to 4/day schedules are available. However, it also has several functional limitations. Programs are in firmware and are not adjustable. Thus, there is no flexibility of dosing times for a given daily frequency. The cap has a limited lifespan (12 months) and is not reusable or reprogrammable. It

is not approved for liquid medications. It has no memory for later reporting of compliance. There is no control over when the cap is opened or the number of dosages taken after the cap is removed. Multiple caps are needed for multiple drug therapies; and the patient is not guided as to how much to take of each medication.

In an article entitled "Medication Monitor for Opthamology" by Yee et al appearing at page 774 of the American Journal of Opthamology, there is described a medication monitor wherein dosing times are recorded in memory for later reporting of compliance. Its functional limits are as follows. There are no alerting features such as an alarm, or clock displays, etc. The electronics provide only a limited memory, i.e. there is no microprocessor to provide alarm and control functions and the limited memory results in limited dosing record resolution. It is only possible to achieve one hour resolution of dosage taken times; and multiple doses within any given hour cannot be recognized. There is no control over when the cap is opened or the number of dosages taken after the cap is removed. Multiple units are needed for multiple drug therapies; and the patient is not guided as to how much to take of each medication.

A sample of the patent literature in this art includes:

U.S. Pat. 3,369,697, Glucksman et al, Feb. 20, 1968
U.S. Pat. 3,968,900, Stanbuk, July 13, 1976
U.S. Pat. 4,223,801, Carlson, Sept. 23, 1980
U.S. Pat. 4,293,845, Villa-Real, Oct. 6, 1981

SUMMARY OF THE INVENTION

The present invention provides a controllable dispenser having significantly improved operational features over known dispensers.

5 The dispenser's operation is based upon a packaging concept that places containers along a flexible strip in a predetermined order. The
containers may be attached to the strip in various
ways. For example, the containers may be integral
10 to the strip material itself, or they could be placed in pockets or sleeves formed in the strip material. Strip materials are typically plastic films that have been heat sealed to form the container holding pockets or adhesive backed fiber
tapes sandwiched around non-sticking sleeves,
15 although many other combinations of materials could provide the same effect. More rigid materials could be used for strip construction, but much more efficient container storage is possible if the strip material is flexible enough
20 to allow the containers to be positioned such that neighboring containers are touching one another. Strip flexibility is also beneficial in insuring smooth movement of the strip around turns in the storage volume. Strip materials should not be so
25 weak that tensile forces occurring during the dispensing operation stretch the strip and alter important container spacing intervals.

Container attachment points are spaced at intervals along the strip that correspond to
engagement location spacings on the dispensing
30 mechanism. These strip and dispensing mechanism spacings permit a rack and pinion type of dispensing operation. Although almost any spacing

interval may be chosen, minimal spacing limitations will arise for given container packing arrangements. For hexagonal closest packing arrangements (as shown in Figure 4), the minimal spacing between containers is approximately one-third the container circumference. Using the nomenclature of Figure 3, $S_{min} \geq C/3$. Parallel packing arrangements (as shown in Figure 5) require a spacing length of at least one container diameter, $S_{min} \geq d$.

Various container shapes and sizes may be accommodated by the dispenser's structural arrangement. Depending upon storage volume design and the shapes of parts of the dispensing mechanism, containers having square, semicircular, or other cross-sections may be acceptable. However, circular cylinders are particularly useful containers, having a shape that packs efficiently for storage, moves freely through the storage volume passageways without jamming, and is reliably engaged by the dispensing mechanism. Containers may be made of any rigid or semi-rigid material. Although more flexible container walls can aid the containers in passage through the storage volume and the dispensing mechanism, too flexible materials might prevent the container from maintaining the approximate shape required for proper engagement by the dispensing mechanism.

Varying container volumes are accommodated by merely changing the length of the container. Since the container cross-section remains the same, a dispensing device design is then possible that accommodates various container volumes by merely changing the height of the storage volume and ejector mechanism. No changes

to the design of the dispensing mechanisms are necessary.

The packaging system of this invention offers several advantages over previously known arrangements. The dispenser is useful for
5 dispensing various kinds of materials, but it is particularly useful for medication dispensing. A wide variety of containers having various diameter to length ratios may be used. By using a container that is leakproof and has a relatively
10 wide opening, a single dispensing device may be used in several different applications. For example, the leakproof 5cc vials used in the medication dispenser/monitor/controller implementation of this design will accommodate
15 almost any medication presentation, including: liquids, suspensions, salves, tablets, capsules, devices, and even multiple compatible substances within a single vial. Further flexibility is provided in that other container volumes can be
20 accommodated by merely changing the length of a container with a given cross section. Only the height of the storage base and ejector pinion need then be changed. Thus, the design and size of the device's dispensing module (containing the
25 electronics and dispensing mechanisms) and the spacing intervals of the flexible strip do not change. One dispensing module may be used with several storage bases and ejector pinions to provide a wide range of container capacities and
30 optimized (minimal volume) package sizes.

Another significant feature relates to individual packaging. The proper amount of the substance to be dispensed is placed in individual containers instead of allowing the user access to

a bulk supply and relying upon him or her to dispense the proper amount. The amount of the substance to be dispensed is precisely metered into the individual containers by the pharmacist/therapist and can be double checked before the device is handed to the user. The same metering precision and reliability over many dispensing operations is not likely to occur when the user must do the measuring or a mechanical device must repeatedly measure and dispense from a bulk supply.

Using individual containers helps prevent contamination and cleaning problems and thereby enhances the economics of such a reusable system. The dispensing device can be used for dispensing one type of substance and, upon completion of the first dispensing program, be immediately reloaded with vials containing a different substance with very little chance of cross-contamination and no substantial cleaning requirements. Bulk or even compartmentalized storage volumes would need extensive cleaning before reuse.

Complete control over dispensing sequencing is provided. The capability of varying the amount and types of substances within each container and organizing these varying contents into a predetermined sequence is a primary feature of the invention. Using the medication dispenser/monitor/controller example, the device could be loaded with vials containing various combinations of drugs in the proper sequence such that a patient on multiple regimens will receive the proper selection of medications according to

the prescribed schedules, and without the patient having to remember any dosing details.

The sequencing feature may also be used to deliver increasing or decreasing amounts of one or more substances over the dispensing period.

5 Thus, a physician using the medication dispenser/monitor/controller to administer medications can taper dosage levels and thereby deliver more effective therapeutic levels while simultaneously minimizing side effects in a manner
10 not possible using level doses.

The dispenser according to the invention is tolerant of any positional orientation. Unlike gravity feed devices, the dispensing device according to the present invention will operate
15 properly in any orientation. The container strip maintains container sequencing and proper spacing regardless of position. Some storage volume characteristics, described later, also help prevent undesirable container movement and thereby
20 contribute to the device's orientation tolerance.

The packaging of containers along a flexible strip forms a flexible rack-like device that, in combination with the pinion-like dispensing mechanism described below, permits the
25 construction of a very compact and reliable dispensing device.

The primary dispensing mechanism includes an ejector element mounted for rotation about its longitudinal axis and having container conforming depressions positioned around its periphery. The
30 ejector acts as a pinion gear that drives a flexible rack, the container strip. When the ejector is rotated, one container is moved from a ready position and out of the dispenser while,

simultaneously, the next container to be dispensed is engaged by a mating ejector depression and moved into the ready position.

Thus, the pinion, the ejector element having depressions that form gear-like teeth, is fixed, and the rack, a flexible strip with attached containers acting as the mating gear teeth, is moved out of the device by pinion rotation. This design offers many advantages:

The first of these advantages is reliability. Using the containers as the 'teeth' on the rack provides inherently more reliable pinion engagement than a conventional flexible strip with rows of small holes used to engage pins on the pinion (as in camera film for instance). Accurate engagement location spacing is essential to jam free operation in both cases. However, the container as sprocket design has only one critical spacing per dispensing operation, whereas for a multiple hole rack, several accurate hole to hole intervals are needed for the same single dispensing operation. Strip manufacture is also simplified by using the containers as sprockets. Punching the multitude of precisely positioned small holes is not required.

The mechanism operates simply. A 1/4 turn of the ejector pinion is all that is required to accomplish a dispensing operation. The container is then outside the device where it can be slid out of its sleeve for use and the empty strip is torn off across the opening edge.

As discussed above, the same dispensing mechanisms may be used to dispense various volume containers merely by changing the length of the ejector pinion to correspond with the associated

container length. Like the container strip, the dispensing mechanism may be operated from any position.

Completed dispensing operations are signalled to a microprocessor by means of lever switches activated by spring loaded actuators riding cams on the shaft used to drive the ejector pinion. The mechanism is designed to activate the signalling switches when the user has completed the 1/4 turn drive shaft rotation. False signals are prevented by using two switches that are alternately, mechanically activated by cams 90° apart and by alternately arming the switches electrically by means of microprocessor output ports. Thus, as soon as a particular switch is activated mechanically, it is deactivated electrically immediately after the signal is received so that further minor motion of the ejector driveshaft is not improperly interpreted as another completed dispensing operation. Simultaneously, the other switch is electrically armed so that it will signal the microprocessor upon the next 1/4 turn rotation and ensuing mechanical activation.

The flexible rack and pinion mechanism described above is the basis for a superior dispensing system having the advantages discussed above. However, in situations requiring the utmost reliability and control, such as the medication dispenser/monitor/controller application, further mechanical and electromechanical features can greatly enhance reliability. The features listed below may be used separately or in various combinations as

required to insure reliable operation in a particular dispensing situation.

The first group of features relates to the housing. The dispensing device components may be housed in two sections. The lower section, the storage base provides a storage volume for the container strip and retains the ejector pinion. The upper section, the dispensing module 46, houses the electronics and all the dispensing mechanisms other than the ejector pinion 34. Both housings may be of one piece, fastenerless construction. The two housing parts are held together by a cabinet lock mounted in the dispensing module, and having a key operated cam that engages slotted extensions of a partition 30 in the storage base. This construction provides several beneficial features.

The tongue and groove mating of the upper and lower housings allows a simple one point locking design having a tamper-resistant joint. Since the user is not given the key to the cabinet lock, there is no easy access to the contents of the dispensing device other than through proper manipulation of the ejector mechanism. Both the storage base and dispensing module are free of external fasteners so that tampering is discouraged and difficult to hide if attempted. The opening in the storage base where containers are ejected is protected against intrusion by the design of the ejector pinion. The sprockets of the ejector pinion are such that they form a close fitting barrier with the storage base partition and thereby prevent viewing of and access to the next container to be dispensed.

There are no unsealed openings in the top of the device through which spilled fluids could reach the electronics and mechanisms. The tongue and groove method of joining top and bottom housings further protects against spills. Since
5 all the electronics and all the dispensing mechanisms except the ejector pinion are mounted in the top housing, any leaking containers are not likely to contaminate those elevated regions. Further protection against leakage contamination
15 can be easily attained by sealing a cover plate over the bottom of the dispensing module, thereby protecting all mechanisms and electronics with one simple cover. A coating provided over the electronics can provide additional protection.

20 Smooth, jamproof, container strip movement is a feature of the storage base design. As shown in Figure 4, the storage base outer wall and inner partition form a generally U-shaped storage volume in which containers are
25 packed both inside and outside the partition. This design provides exceptionally efficient (compact) container storage while simultaneously providing passageways through which the container strip can move smoothly without jamming.

30 By keeping all passageways a little less than two container diameters "d" (See Figure 3) in width, containers cannot get past one another and out of sequence. Thus, impact forces cannot rearrange container sequencing and cause
35 containers later in the sequence to engage the ejector pinion ahead of earlier containers and jam the mechanism. Because a minimum passageway width of 1.87 diameters is needed to allow double row, closest packing as is desired in some areas, the

passageway widths in those regions are typically kept between 1.87 and slightly less than two (2) diameters.

The U-shaped design allows for smooth container strip movement since there are only two partition turns, at a maximum, for the containers to negotiate. The radii of the turns are large enough, compared to the inter-container spacing, so that most contact with the partition is by the containers and not the spacing intervals. Because the containers only have line contact with the partition wall, very little frictional force is generated and the containers move smoothly around the turns. Tighter radii would allow more strip contact with the partition wall and produce larger drag forces that might bind strip movement. Circular storage volumes, having capacities as shown, are not preferred because they have housing proportions that are hard to hold in one hand. Similarly, even though longer, rectangular designs can have fewer turns, the extended housing length can make portable units awkward to carry.

The two part housing design is also beneficial to the user who may want the capability of dispensing several different capacity containers with a minimum equipment investment. Since all electronics and mechanisms other than the ejector pinion are contained in the top half dispensing module, container capacity can be changed merely by using a container of the appropriate length to give the volume desired, and by using a storage base and ejector pinion of corresponding length. No change in dispensing module size or design is required. Thus, one dispensing module can be used with several

different height storage bases, ejector pinions and containers to produce a broad capability dispensing system.

5 There are several mechanisms associated with control of ejector pinion motion that help insure reliable operation.

10 A pin 92 located in the storage base (See Figure 22), under a groove in the ejector pinion, prevents further ejector rotation until the dispensed container is removed. This pin prevents inadvertent, or intentional, attempted insertion of containers back into the unit which could jam the ejector mechanism.

15 The two alternately acting ejector switch actuators described above have a second function. The depressions in the drive shaft that engage the spring loaded actuators are shaped so that the drive shaft cannot be turned in the reverse direction once an actuator has seated. Thus, the drive shaft can be turned backwards at most something less than one-quarter turn and not at all once the fully dispensed position is reached. By preventing reverse ejector rotation, containers are prevented from being intentionally or inadvertently pushed back into the storage volume and thereby possibly jamming the dispensing mechanism, or disengaging the ejector pinion.

25 Pins are arranged in the top of the ejector pinion such that they extend into the dispensing module. A notched locking wheel 86 is positioned in the top housing so that its circumference will prevent ejector pinion rotation unless the notch is so aligned as to allow the adjacent ejector pinion pin to rotate forward. The notch is so designed that as the ejector

30

pinion rotates forward a pin engages the notch well and forces the locking wheel to rotate before disengaging the notch. Once the locking wheel is turned, the notch is no longer in a position such that the next ejector pinion pin can move forward, and the ejector pinion is thereby locked.

Thus, ejector pinion locking occurs automatically and mechanically each time a container is dispensed. This auto-lock feature prevents the operator from inadvertently dispensing too many containers by rotating the ejector pinion more than 90 degrees. Being mechanical and automatic, the mechanism requires no computer logic or power to perform this function. This locking design also permits a simple, but effective, computer controlled unlocking feature that can be used to better insure operator conformance to a predetermined dispensing schedule.

Where restricted access to the containers is not important, a simple mechanical linkage can allow the operator to manually reset the locking wheel so that the notch is aligned to permit another dispensing operation. In other situations, where precise control over the dispensing operation is desired, a solenoid controlled by the dispensing device's microprocessor can be easily put in control of the locking wheel. When an electrical pulse is supplied to the solenoid, it rotates the locking wheel 86 in the reverse direction (approximately 45° in this example) so that the notch 90 is moved into the unlocked position.

Although a linear acting solenoid with linkages can be used to reverse rotate the locking

5 wheel into its unlocked position, no linkage is
necessary if a rotary acting solenoid is used and
a simpler, more reliable design results. The
choice of a rotary solenoid over a linear solenoid
also greatly increases the impact resistance of
the dispensing mechanism. Linear
10 acceleration/deceleration forces (due to impacts,
for instance) in the direction of the longitudinal
axis of the plunger of a linear solenoid could
cause the locking mechanism to lock or unlock when
not intended. Since linear forces produce
balanced and opposed forces when acting on a
rotational mass, impact forces do not tend to
cause inadvertent armature motion when a rotary
solenoid and locking disc are used.

15 Further means of insuring that
lock/unlock positions of the locking wheel are
retained can be provided through the use of
latching forces. Latching mechanisms increase the
force required to move the locking wheel out of
20 either one of its bistable positions. One form of
the latching mechanism utilizes three magnets:
one on the locking wheel, and two others mounted
such that they are adjacent the locking wheel
magnet and providing attractive (latching) forces
25 when the wheel is in its lock and unlock
positions. Although there are many other possible
latching designs (such as spring loaded rockers),
the described magnetic system uses just three
simple parts that can be easily adjusted to
30 provide the optimum latching forces. By adjusting
the magnets' residual field strengths during
magnetization, the resultant latching forces may
be made just sufficient to prevent accidental
motion of the locking wheel with no excess force

that would require the use of a larger and higher power consuming solenoid. Since a rotary solenoid greatly reduces the latching forces required because of its inherent stability under linear forces, the torque requirements of the design are minimal.

5
A lever switch ("status" switch) adjacent a cam on the locking wheel is used to signal to the microprocessor the status of the locking/unlocking mechanism. This provides a
10 check to see that the locking wheel has been able to respond properly to commands from the microprocessor. If, for instance, the user has prevented locking wheel reset by applying restraining forces through attempted drive shaft
15 rotation during the solenoid pulse, this switch will alert the microprocessor to the need for sending additional pulses to the solenoid until the unlocking operation has been successfully completed.

20 The dispensing device described above can certainly perform all its functions, with all the stated benefits, from a fixed location using externally supplied power. However, the structure has been particularly optimized for portable
25 operation using self contained batteries. Portability is especially beneficial to the medication dispenser/monitor/controller application where small size and battery operation are essential.

30 Several features contribute to efficient utilization of space within the unit:

a. Hexagonal, closest packing - much of the storage volume is configured for double row, closest packed storage which results in maximum

container densities. The flexibility of the container strip allows the containers to be pushed next to one another to accomplish closest packing.

5 b. Optimum partition design - the U-shaped partition folds the container strip into a compact area while providing large radius turns that help insure smooth strip movement. Virtually the entire area inside and outside the partition may be filled with containers. Single row
10 designs, such as one using a spiral partition in a round enclosure, require more extensive partitions that waste space and have more turns that increase the undesired drag forces on the strip as it is advanced. On the other hand, use of too few
15 partitions risks the possibility that containers will not advance in the proper order and thereby jam the dispensing mechanism.

 The U-shaped design also affords the most easily grasped and carried device proportions. Round devices having comparable capacities have
20 diameters that are too large to comfortably grasp without a handle. More rectangular designs of similar capacity have a length dimension that becomes more awkward to accommodate during transport and storage.

25 c. Minimum wall thickness - The outer wall and partition thicknesses have been minimized to save volume and weight. Using extensions of the storage base partition, instead of a base mounted post, to engage the upper housing cabinet
30 lock maximizes the space available for container storage.

 d. Housing adaptability - The placement of all electronics and dispensing mechanisms in the top portion of the device allows the height of

the separate storage base to be adjusted to exactly fit the height of the containers.

e. VLSI circuits - Very large scale integrated circuits are used, each of which perform the function of several circuits in just one package, thereby saving large circuit board areas and reducing unit weight.

f. Plastic construction - Almost all housing and support structures, as well as several of the dispensing mechanisms, may be suitably constructed of plastic materials, thereby lessening the weight that must be carried.

g. Software features - By implementing in software several functions normally implemented in hardware, valuable space and weight are saved. The usual UART (Universal Asynchronous Receiver/Transmitter) and parallel interface hardware elements have been implemented in software. Serial communications are used to simplify the hardware necessary for communications with the Base Unit. The level shifting circuitry needed by the communications link has been moved out of the dispensing device and into the Interface Unit to save more dispensing device space.

So that the dispensing device could be used in applications such as the medication dispenser/monitor/controller where the battery power supply must provide up to 60 days or more of continuous operation, many power saving features have been implemented.

a. CMOS circuitry - All integrated circuits are of Complementary Metal Oxide Silicon construction for lowest possible current draw.

b. 'WAIT' mode - The use of a microprocessor having a low power standby operating mode and software that places the MPU in that power saving mode for more than 98% of its operating period is the major power saving feature.

c. Piezoalarm - The reminder alarm function is implemented with a piezoelectric element that uses only a few milliamperes of current. Further power savings result by only pulsing the alarm for a fraction of every minute.

d. LCD - A liquid crystal display is used as the visual dispensing reminder because it uses only microamperes of current.

e. Mechanical auto-lock - The auto-lock feature requires no electrical power, the motive force being supplied by the dispenser operator while advancing the ejector pinion drive shaft.

f. Manual ejector drive - Although the ejector pinion could be motor driven to ease the dispensing operation for the fixed location user where external power is readily available, the manual drive design permits portable operation where the large amount of power required for an electric drive is not available.

g. Rotary solenoid - As described above, a rotary solenoid requires less latching forces and therefore less starting torque (power) than a linear solenoid design. Rotary solenoids also provide superior starting torque for a given current and size. The unlock mechanism is designed so that the unlock solenoid need merely rotate a lightweight locking wheel. No linkage forces have to be overcome that would require the use of a bulkier, higher current draw solenoid.

Further, the solenoid driving software routine sends only a 50 msec pulse of power to the solenoid, limiting power used to the minimum needed to accomplish reliable unlock operation. Only pulses of power need be sent to the unlock solenoid since the mechanism is latched once it reaches the unlock position and no further power is needed to maintain the proper position.

5 h. VLSI circuitry - The use of highly integrated circuits reduces power consumption compared to discrete devices performing the same functions.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a block diagram of the medication dispenser and compliance monitor system according to the present invention;

15 FIGURE 2 is an exploded, partially cut-away view of a field unit 24;

FIGURE 3 is a schematic representation of containers on a strip showing dimensions and spacings;

20 FIGURE 4 is a top view of the storage base portion of the Field Unit showing containers to be dispensed stored therein;

FIGURE 5 is a schematic representation of an alternative container storage arrangement;

25 FIGURE 6 is a schematic representation of an integral strip and storage container;

FIGURE 7 shows a strip arrangement including two portions heat sealed to one another;

30 FIGURE 8 shows a two portion strip 50 with a container held between the two strip portions;

FIGURE 9 shows a container with a separate plug cap;

FIGURES 10-12 are schematic diagrams showing a dispensing operation;

5 FIGURES 13 and 14 are side views of a portion of the dispenser module showing how a dispensing operation is signalled;

FIGURES 15 and 16 are schematic views further illustrating how a dispensing operation is signalled;

10 FIGURES 17-19 are schematic illustrations demonstrating the automatic locking mechanism;

FIGURE 20 is a side view showing the operation of the locking wheel by the rotary solenoid;

15 FIGURE 21 is a top view of ejector pinion 34 showing the position of the container stop pin;

FIGURE 22 is a cross sectional side view showing the position of the container stop pin;

20 FIGURE 23 is a cross section view of the assembled Field Unit;

FIGURE 24 is a view looking up at the dispensing module portion of the field unit;

25 FIGURES 25 a and b are a schematic diagram of the electronic subsystem of the field unit;

FIGURE 26 is a flow chart of the software controlling the operations of the field unit;

FIGURE 27 is a schematic diagram of the interface unit 22;

30 FIGURE 28 is a block diagram of base unit 20;

FIGURE 29 is a flow chart of the base unit loading routine software for loading a field unit;

FIGURE 30 is a flow chart of the base unit unloading routine software for debriefing a field unit after it has dispensed some or all of its containers;

5 Appendix I is a detailed listing of the software controlling the field unit;

Appendix II is a detailed program listing of the loading routine shown in flow chart form in figure 29; and

10 Appendix III is a detailed program listing of the debriefing routine shown in flow chart form in figure 30.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

System Overview

Referring first to FIGURE 1, there is
15 shown a block diagram of the overall system concept of the present invention. The system includes a single base unit 20, a single interface unit 22 and a plurality of field units 24-1 . . .
20 24-N. A drug therapist or researcher can program many field units 24 (one at a time), give them to different patients or subjects and later collect and debrief them and prepare compliance reports.

To prepare a field unit 24 for
distribution to a patient or test subject, a
25 medication package, such as package 26, is first loaded into field unit 24. The field unit is then electrically connected with interface unit 22 and a programmed drug regimen, defined by the
therapist by interacting with base unit 20, is
30 loaded via interface 22 into the field unit. The drug therapist defines the drug regimen by using

the "LOAD-M" software (set forth in Appendix II) with base unit 20 to configure the field unit 24.

5 The loaded field unit 24 is given to the patient, who dispenses medication in accordance with the schedule loaded into it using the "LOAD-M" software. The dispensing operation is governed by the software stored in field unit 24 and listed in Appendix I. This field unit software provides dosing time prompts, controls the dispensing mechanism, and stores the actual times and dates of dispensing.

10 After the drug regimen is completed, field unit 24 is returned to the therapist where it is again connected to base unit 20 via interface 22. The field unit is then debriefed according to the software listed in Appendix III and the base unit prepares a report to the therapist as to exact times of dispensing and any departures from the desired schedule.

Field Unit Mechanics

20 Referring to FIGURES 2-24 there are shown the mechanical details of a field unit 24.

Referring first to Figure 2, there is shown an exploded view of field unit 24. Field unit 24 includes a storage base 28 constituting a portion of the housing of the field unit. Inside of storage base 28, there is fitted a storage base inner partition 30 which, together with an outer wall 32 of the storage base defines a passage way within which a dispensing package 26 can be stored and from which individual containers can be dispensed. The dispensing action is carried out by the rotation of an ejector pinion 34 which is manually rotated by the user by manipulation of a

knob 36, during times when the field unit is "unlocked" in accordance with a predetermined dispensing schedule stored in it. The unlocking mechanism operates under microprocessor control as will be described later in further detail.

5 Inner partition 30 includes two slotted extensions 38 and 40 which pass through a hole 42 in a plate 44 and ultimately engage with a cam lock (not shown in Figure 2) in a dispensing module portion 46 of Field Unit 24. Dispensing
10 module portion 46 includes various mechanical elements, electronic subsystem, display, alarm, etc. A slot 48 on the upper surface of dispensing module portion 46 accommodates a key for a cam lock.

15 Dispensing package 26 includes a strip 50 holding a plurality of individual containers 52, each having its own cap 54. Package 26 is fitted into the passageway defined by outer wall 32 and inner partition 30 of storage base 28 according to
20 a predetermined sequence. Each time a container 52 is to be dispensed, ejector pinion 34 is rotated so as to engage a single container 52 and push it through an opening 56 in outer wall 32 of storage base 28. Ejector pinion 34 is rotated by
25 the user by means of rotating drive shaft Knob 36.

 Ejector pinion 34 includes four locking pins 58 which cooperate with an unlocking arrangement for controlling when ejector pinion 34 can be rotated in accordance with the pre-
30 determined schedule. Ejector pinion 34 includes four concave portions 60 for accommodating the shape of individual containers 52 so that a container fits within concave portion 60 and is conveyed by rotation of the ejector pinion.

Referring now to Figure 3, there is shown a schematic representation of a portion of a medication package 26 including strip 50 and two (2) containers 52. Each container has a circumference "c" and a diameter "d". There is a space "s" separating two adjacent containers 52.

Referring now to Figure 4, there is shown a top view of storage base 28 of field unit 24 with the dispensing module portion 46 removed. This figure shows a plurality of containers 52 packed within the passage way defined by inner partition 30 and outer wall 32. The arrangement of containers 52 shown in this Figure where the passageway is widest represents what is known as "hexagonal closest packaging" which allows the maximum number of containers 52 to be stored within the passage way volume. The minimum inter-container strip spacing required for closest packing is shown as the length S_{min} . The numbers shown inside each of containers 52 represent the sequence of dispensing of the individual containers. First, container #1 is dispensed, then container #2 is dispensed, etc. Each dispensing operation corresponds to a $1/4$ turn of ejector pinion 34. As individual containers 52 are dispensed, strip 50 is pulled and the undispensed containers advance through the passage way as necessary toward ejector pinion 34.

Referring now to Figure 5, there is shown an alternative, but not preferred, packaging arrangement of containers 52 known as "parallel row packaging". The numbers inside each of containers 52 represent the sequence of dispensing of the containers. The minimum inter-container

strip spacing required for parallel row packing is shown as the length S_{min} .

Containers 52 can either be formed integrally with strip 50 as shown in Figure 6 or the containers can be fitted within spaces formed in strip 50 to accommodate the containers. As shown in Figure 7, strip 50 can be formed from two separate and distinct strips of material 62 and 64 which can be sealed adjacent to container areas. The individual containers 52 can then be inserted into the space defined by the two strips of material.

Referring to Figure 8, there is shown such an arrangement including strips of material 62 and 64 with a container 52 inserted therein.

Referring now to Figure 9, there is shown a more detailed view of a portion of medication package 26. Each container 52 can be fitted with its own plug cap 66.

Referring now to Figures 10, 11 and 12, there are shown top views of the portion of storage base 28 including ejector pinion 34. These figures illustrate the dispensing sequence for containers 52. As in the preceding figures, the numbers shown in the centers of respective containers 52 indicate the dispensing sequence of containers 52. As shown in Figure 10, the first container is engaged in a concave portion of ejector pinion 34. This first container 52 is positioned along strip 50 in accordance with the details shown in Figure 3 with a spacing s between containers #1 and #2, the distance between concave portions of ejector pinion 34 also being equal to said length S . Ejector pinion 34 rotates in the direction shown by arrow 68. Figure 10 shows the

position of containers #1, #2 and #3 just before
ejector pinion 34 is rotated its quarter turn to
dispense container #1. In Figure 11, ejector
pinion 34 has been rotated 1/8th turn from its
starting position and container #2 is already
5 engaged in the next concave portion of ejector
pinion 34. Figure 12 shows ejector pinion 34
rotated a full quarter turn from its position
shown in Figure 10 and with container #1 dispensed
through opening 56 of storage base 28. For the
10 sake of drawing convenience, in Figure 11, strip
50 is shown with some "slack" around Fig. 70 of
ejector pinion 34. In reality, there would be
little slack since the spacing S between
containers is carefully selected so that there
15 will be no slack. As shown in Figures 10-12,
ejector pinion 34 conforms to the space defined by
outer wall 32 and inner partition 30 so that there
is very little clearance between the tips 70 of
ejector pinion 34 and the wall and partition
20 portions of storage base 28. This protects the
containers from being tampered with or removed
before ejector pinion 34 is unlocked for
dispensing. After a container 52 is dispensed, as
shown in Figure 12, the container 52 may be
25 removed from strip 50 and the protruding portion
of the strip 50 can be torn off at the edge 33 of
wall 32 and discarded.

The operation of field unit 24 is under
the control of a microprocessor. The
30 microprocessor periodically unlocks a locking
mechanism so that the user can manually dispense
the next container in sequence. However, the
operation is considerably more sophisticated than
merely unlocking at predetermined intervals of

time. It can unlock based on a predetermined formula including predetermined intervals and also as a function of when actual dispensing has taken place. Therefore, it is important that the microprocessor know exactly when the user has
5 dispensed a container.

Referring now to Figures 13-16, there are shown drawings of portions of the field unit 24 for annunciating that a dispensing operation has been completed and for preventing reverse rotation
10 of ejector pinion 34.

Referring first to Figure 13, ejector pinion 34 is driven by a drive shaft 72 having cams 74 and 76 (Cam 74 is not fully visible in Figure 13). Drive shaft 72 is rigidly coupled to
15 knob 36 which is rotated by the user to cause a dispensing operation. Cams 74 and 76 engage spring loaded switch actuators 78 and 80 which in turn operate ejector switches 82 and 84. Cams 74 and 76 each include two cam portions spaced 180°
20 apart around drive shaft 72. They are oriented around shaft 72 so that closest portions of cams 74 and 76 are spaced 90° from one another around periphery of drive shaft 72 so that they will cause a closure of switches 82 and 84 at 90°
25 intervals of the rotation of drive shaft 72. Figure 13 shows a position of drive shaft 72 whereat actuator 78 is engaged with cam 74 thereby turning switch 82 "on". As shown in Figure 13, at the time switch 82 is "on", actuator 80 is not
30 engaged with cam 76 because cam 76 is out of position of drive shaft 72 so that it cannot be engaged. Therefore, actuator 80 is not engaged with cam 76 and switch 84 is therefore "off".

Figure 14 shows the same components as shown in Figure 13, but later in time, after drive shaft 72 has been rotated 90 degrees, so that cam 76 is engaged by actuator 80. As shown in Figure 14, when actuator 80 is engaged in cam 76, switch 84 turns "on". Cam 74 is then out of position so that actuator 78 cannot engage it. Therefore, switch 82 is "off".

Referring now to Figures 15 and 16, this process of signalling a complete dispensing operation is further illustrated.

Referring now to Figure 15, actuator 78 is shown engaged with cam 74, thereby causing switch 82 to be "on". This corresponds to the position shown in Figure 13. At the same time, actuator 80 is not engaged with cam 76 and therefore switch 84 is "off".

Figure 16 shows the same components as shown in Figure 15, but 1/4 rotation of drive shaft 72 later. Actuator 78 is not engaged with cam 74, but actuator 80 is engaged with cam 76. Therefore, switch 82 is off and switch 84 is "on". The "on" and "off" status of ejector switches 82 and 84 signal to the microprocessor when a dispensing operation is complete. This corresponds to completion of a 1/4 turn of drive shaft 72 rotation.

In addition, the shape of the cam depressions on drive shaft 72 are such that they prevent reverse shaft rotation when an actuator 78 or 80 is seated in its corresponding cam. The seating action is abrupt and concurrent only with a complete 90° drive shaft rotation to avoid ambiguous signalling. The microprocessor is programmed to electrically deactivate a switch 82

or 84 immediately after it has been mechanically activated. By using two switches that are alternately enabled and activated by a completed dispensing operation, erroneous multiple signals that could occur if only one switch were used are avoided.

The unlocking mechanism will be discussed with reference to Figures 17, 18 and 19. Ejector pinion 34 interacts with a locking wheel 86 which controls a locking wheel switch 88 for signalling the microprocessor as to the "locked" or "unlocked" status of field unit 24. As shown in Figure 17, locking wheel 86 includes a notched portion 90. The locking wheel 86 is positioned such that notched portion 90 can interact with locking pins 58 of ejector 34. Viewed from above, the locking wheel 86 is above that portion of ejector 34 including tips 70, as shown in Figures 18 and 19. Locking wheel 86 is rotated by interaction with locking pins 58 between those positions shown in figures 17 and 19. A rotary solenoid 212, not shown in this Figure, can reset the locking wheel 86 from its locked position in Figure 19 to its unlocked position in Figure 17.

As shown in Figure 18, a locking pin 58 of ejector pinion 34 engages notch 90 in locking wheel 86 and rotates the locking wheel 86 towards the "locked" position. Thus, rotating ejector pinion 34 during a dispensing operation, causes locking wheel 86 to change positions. Engagement of the next locking pin 58 with locking wheel 86, as shown in Figure 19, prevents further ejector pinion rotation. This automatically locks the dispensing device upon completion of a dispensing operation. Thus, Figure 19 illustrates a "locked"

position, resulting from the counter-clockwise rotation of locking wheel 86 as a result of clockwise rotation of ejector pinion 34. When it is time to unlock the dispensing device, the microprocessor actuates the solenoid to rotate locking wheel 86 backwards, i.e., clockwise, into the unlocked position, shown in Figure 17, thereby allowing the user to carry out the next dispensing operation.

Referring now to Figure 20, there is shown a view of locking wheel 86 coupled so as to be operated by a solenoid 212. A pulse from the microprocessor to solenoid 212 causes locking wheel 86 to rotate from the position shown in Figure 19 to the position shown in Figure 17.

Referring now to Figures 21 and 22, the container stop operation will be explained. Container stop pin 92 is mounted in a bottom plate 94 of field unit 24. Ejector pinion 34 includes notches 96 for clearing the stop pin during ejector pinion 34 rotation. In effect, stop pin 92 prevents further ejector pinion 34 rotation until the dispensed container 52 (shown in Figure 21) is removed. Thus, pin 92 prevents inadvertent or intentional attempted insertion of containers back into the unit which could jam the dispensing mechanism.

Referring now to Figure 23, there is shown a cross sectional view of field unit 24 in an assembled condition showing both dispensing module portion 46 and storage base 28. Slotted extension 40 of partition 30 is engaged by a cam lock 96 for securing dispensing module 46 and storage base 28 in an assembled condition. The electronic subsystem including the microprocessor

is formed on a circuit board 98 within dispensing module portion 46. The electronic subsystem is powered by a battery 200. A second battery 202 provides power for operating the solenoid. Circuit board 98 has mounted thereon a liquid
5 crystal display 204 for displaying information to the user through a window 206 in the upper surface of dispenser module portion 46. Knob 36 for effecting a dispensing operation is shown in the upper right corner of this figure. Dispensing
10 module portion 46 also includes a piezo electric alarm 208 for sounding an audible alarm through an opening 210 to alert the user that it is time to dispense a dose of medication.

Referring now to Figure 24, there is
15 shown a view looking up into the dispenser module portion 46 of field unit 24. Ejector pinion 34 is not shown in this figure. Three conductor connector 216 provides interconnection to interface unit 22. Push button switch 214 allows
20 the user to reset the microprocessor 100 to signal a base unit 20 request.

Field Unit 24 Electronic Subsystem

Referring now to FIGURES 25(A) and 25(B), there is shown a schematic diagram of the
25 electronic subsystem hardware of a field unit 24. The functions of electronic subsystem are as follows:

1. It provides RAM (random access memory) for approximately 131 bytes (or more) of
30 information. Fifty of these bytes correspond to 50 alphanumeric characters that define dosing schedule and identifying data. The remaining 81 bytes

of memory are used to store one byte which holds the dosage taken count and 80 bytes that contain the date and time data when up to forty dosages have been taken. The size of the RAM required is a function of the number of dosages that can be delivered and the amount of identifying data desired.

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2. It provides information as to the real or related time of day and date. This information is made accessible to the microprocessor for the purposes of recording dosing times and for schedule checking.
3. It provides signalling element(s) to indicate to the microprocessor when a dosage has been dispensed.
4. A signalling element is provided to indicate that the ejector locking mechanism is in its locked position.
5. A communications path is provided for sending data to and receiving data from interface unit 22 and base unit 20.
6. A clock display with its associated driver circuitry is provided to display the next dosing time (including AM/PM and proper day indicators).
7. An ejector unlock mechanism and associated driver circuitry is provided such that access to dosages is under field unit electronics control.
8. An audible alarm with its associated circuitry is provided such that the monitor user can be alerted to an impending dosing time.

9. Programmable logic and control circuitry are provided for integrating the above eight functions into an effective unit.

These functions are carried out by the electronic subsystem which is microprocessor-based and under the control of software flow charted in FIGURE 26 and listed in Appendix I. The electronic subsystem features low power consumption such that it can operate from a single small battery for a period of time that will accommodate the longest possible dosing schedule that could be programmed into the unit. Solenoid 212 is powered by a separate solenoid battery 202 so that voltage swings due to solenoid operation will not affect electronic subsystems. Battery operation affords maximum portability and allows more convenient refrigeration, if required. The electronic subsystem has high noise immunity so that operation is not affected by spurious inputs, ambiguous data and address bus signal levels, or supply voltage fluctuations.

The electronics subsystem provides the above-listed functions and features in the following manner.

The programmable logic and control circuitry along with 112 bytes of RAM (random access memory) are provided by a Motorola MC146805E2 microprocessor unit 100, a NMC27C16 EPROM 102, a 74C00 address decode unit 104, and a 74HC373 Address Latch 106. The microcomputer supports the minimum volume requirement by including on one chip 112 bytes of user RAM, timer circuitry, 16 input/output lines, and the means to simulate a UART (universal asynchronous receiver/transmitter) communications interface to

the interface/base units. Of the 112 bytes of user RAM available, one byte contains the dosage taken count, 80 bytes are used to store up to 40 sets of delivered dosage date and time data, and the remaining 31 bytes are used for intermediate results and stack space. Up to 2048 bytes of program storage is provided by the UVEPROM (ultraviolet erased, electrically programmable, read-only memory). The 74C00 quad NAND gate decode unit and the 74HC373 latch allow the microprocessor to properly access the EPROM.

The timekeeping function is provided by the Motorola MC146818 real time clock plus RAM 108 and a 32.768 kHz crystal oscillator circuit 110. The real time clock retransmits the 32.768 kHz signal it receives from the crystal oscillator to supply the clock input the microcomputer requires. Crystal oscillator accuracy is approximately $\pm 0.005\%$ which amounts to an error of about 3 minutes in forty days, the maximum usage period as presently designed. Although the real time clock resolves time to the second, our present system only uses one minute resolution as this is more than sufficient precision for the immediate application. Another function of the real time clock is to, by means of its programmable alarm circuitry, supply a once-per-minute interrupt signal to the microcomputer's timer input where a once-per-minute timer interrupt is generated. System integration is supported by the 50 bytes of user RAM included in the real time clock. These 50 bytes of memory are used to store the identifying and dosing schedule data sent to the field unit during the monitor loading operation.

Microswitches 82, 84, operated by activators 78 and 80, respectively, riding on ejector drive shaft cams 74 and 76, provide the signalling means to indicate the delivery of the next dosage. The ejector drive shaft cams 74 and 76 and the microswitches' 82 and 84 orientation are such that the microswitches are alternately operated as dosages are sequentially delivered. By alternatively enabling the two microswitches 82, 84 electrically by means of output lines PA7 and PA6, a reliable indication of dosage delivery without danger of spurious, multiple signals is accomplished.

A locked ejector condition is signalled to the microcomputer by means of microswitch 88 activated by the ejector locking wheel and connected to input line, PA1.

Communications to the field unit are brought in on input line PA0, and data leaves the microcomputer through output line PA5 on its way to the interface and base units. Communication protocols are provided by UART programs in the EPROM. Baud rate generation is derived from the microcomputer clock frequency. Serial, rather than parallel, formats are used to simplify the communications interface and to permit the widest possible application to a variety of possible base units. The data format presently preferred is 110 baud rate, 8 bit word length, no parity bit, 1 stop bit, and XON/XOFF status disabled.

Liquid crystal display 204 with an ICM7211AM display driver 114 is used to provide next dosing time information to the user. Six output lines, PB0-PB5, are used to update the

driver and display after a dosage has been delivered.

Rotary solenoid 212 is used to release (unlock) the ejector locking mechanism under microcomputer control. A separate 4.2 volt battery 202 is used to energize the solenoid circuit since the large current draw causes voltage spikes that would interfere with proper microcomputer operation if a common battery were used. ULN2069 quad Darlington switches 112 provide a high current buffer for the microprocessor control line PB6.

The audible alarm function comprises a piezoelectric element 208 and driver circuitry 116. The driver circuit 116, including a transistor 118 and three resistors, serves to drive the piezoelectric element into oscillation, thereby producing an alarm.

Low power consumption is attained by using

1. All CMOS (complementary metal oxide silicon) circuitry.
2. A relatively slow clock rate (32.768 kHz).
3. Liquid crystal type clock display.
4. Piezoelectric type alarm element.

Consequently, a TR133 4.2 volt mercury battery 200 can power the entire circuit, exclusive of the solenoid, under worst case conditions, and for the maximum period of forty days and still retain a large reserve charge.

High noise immunity is attained by using:

1. All CMOS circuitry with its wide noise margins and wide supply voltage limits.

2. Use of a separate battery for solenoid power.
3. Serial communications with error checking routines.

Minimum volume is attained by using:

- 5 1. Microcomputer on a chip. The MC146805E2 contains a microprocessor, 112 bytes of user RAM, timer, and 16 I/O lines, and can be programmed to perform the functions of an UART.
- 10 2. Multifunction real time clock. The MC146818 includes 50 bytes of RAM and an alarm interrupt.

Further integration and volume reduction is certainly possible through presently, or soon to be, available VLSI (very large scale integration) components that combine the microcomputer and real time clock functions, or the microcomputer and ROM functions, or even the microcomputer, ROM, and display driver functions. The ultimate in integration is also possible by means of customized CMOS gate arrays that could conceivably contain all the integrated circuit packages presently shown in our present design.

Field Unit Software

25 Referring now to FIGURE 26 there is shown a flowchart of the software associated with the FIGURE 25 hardware. A detailed program listing is set forth in Appendix I.

30 Program execution begins either after a power on reset (Step 300) (i.e. installation of a battery) or upon a hardware reset (Step 304) (i.e. pushing a reset switch 214) (see Figure 25A) A power on reset is not meaningful except that it

insures an orderly configuration of the microprocessor inputs and outputs immediately without the need of further operator action.

After a power on reset, the program halts at a safe point (no outputs activated) and waits for
5 the proper beginning of operation.

Normal program execution begins when the reset switch is pushed by the operator to signify a base unit request (see Step 304). This request may be either to load the field unit with data
10 prior to use by the patient or it may be to have the field unit unload the data collected during the term of the patient's use of the Monitor. In either case the first action taken is to configure the microprocessor's input and output ports for
15 proper operation. This routine is named "Reset" (Step 302).

Next, in the "Recogn" (recognition) routine (Step 306), the field unit first sends an ASCII "R" ("ready") to the base unit to indicate
20 that communications may start and then waits to receive an ASCII character from the base unit in order to identify what function is being requested. If the received character is a "L", then the program jumps to the "Load" routine (Step
25 308). If the character is an "U", then the program jumps to the "Unload" routine (Step 310). If the character received is neither a "L" nor an "U", then a problem has occurred during communications and the program goes to the
30 "Badcom" ("bad communication") section (Step 312).

The "Badcom" routine sends a "?" to the base unit to alert it to the communications problem and then the program jumps to "Wait" (Step

314) where it waits for another push of the reset button to restart the program.

When the field unit recognizes a base unit request to "Load", it proceeds to receive, echo, and store 50 bytes (characters and numbers) of data sent by the base unit. This data includes patient and study identifying information and the dosing parameters data. The information is received as ASCII coded characters that are echoed to the base unit to insure accurate data transfer and then stored in the real time clock user RAM area for later use. The "Load" routine also allows the operator to verify the proper operation of the field unit's alarm and unlock functions before placing the unit into service.

After loading is complete the program enters the "Start" routine (Step 316). Here the real time clock is set to the actual time and is configured to provide a once-a-minute timer interrupt to the microprocessor. Registers in the microprocessor are initialized, the liquid crystal clock display 204 is set to show the first scheduled dosing time and finally, the real time clock is started running. The program then goes to the "Minute" section (Step 318) where the field unit begins user related operations.

In the "Minute" routine, which is reached once per minute via a timer interrupt, the microprocessor first reads the real time clock and stores the present hours and minutes to compare against the events schedule. The following checks are made and appropriate action taken:

1. Is it midnight? If so, increment day counter.

2. Should the piezoalarm be activated? If so, sound alarm 4 times.
3. If the ejector should be unlocked and is not, a pulse is sent to the solenoid to reset the locking wheel.

5 After completing these tests, the program exists to the "Wait" routine.

For all but a few seconds each minute the program is idling in the "Wait" routine. While in this routine, the microprocessor is in its "Wait" operating mode which disables all functions except the ability to respond to interrupts and resets. This results in very low power consumption which allows the field unit to operate on a small battery for a period of at least 40 days. While
10 in this state, the microprocessor performs no task and simply waits for one of three events to occur.

Once every minute the real time clock will initiate a microprocessor timer interrupt (Step 320) that causes the program to exit "Wait" and go to "Minute" where the alarm and unlock checks will be made as described above. Upon completion of the "Minute" functions, the program returns to "Wait" and awaits the next interrupt.
20

The delivery of a dosage and the accompanying activation of an ejector switch 82 or 84 (Step 322) will also cause the program to exit "Wait" by means of activating the microcomputer's external interrupt line. In this case the program jumps to "Dosage" (Step 316) where:
25

- 30 1. The dosage counter is incremented.
2. Date and time of dosage delivery data is stored in the microprocessor's user RAM.
3. The program jumps to "Minute" where the events schedule is checked.

After these tasks are completed the program once again returns to "Wait" to await the next interrupt or reset.

The third method of exiting "Wait" is the activation of the reset switch, signalling a base unit request. The servicing of a "Load" request was described above. An "Unload" request is now described.

At the end of the dosing period the field unit is returned to the doctor by the patient. The base unit program for field unit interrogation will request the operator to push the reset switch. The field unit program exits the "Wait" routine, passes through "Reset" to the "Recogn" section where the unload request is recognized, and then jumps to the "Unload" routine. This part of the program sends the original 50 bytes of identifying and dosing schedule data stored in the real time clock RAM back to the Base Unit. The 81 bytes of dosing data stored in the microprocessor's RAM are then sent to the base unit. The field unit checks for an accurate echo from the base unit after each data byte is sent. After data transmission is complete the field unit program goes back to "Wait". If any echo shows that a data transfer error has occurred, the "Unload" program is aborted and a jump is made to "Badcom" where an error flag is transmitted as described earlier.

Interface Unit

Referring now to FIGURE 27 there is shown a schematic diagram of interface unit 22 and the communication lines of base unit 20.

The purpose of the interface unit 22 is to provide signal level shifting such that the field unit can send and receive serial communications to and from any base unit 20 having an RS-232-C standard serial communications port. By means of this interface unit 22 the compliance monitor system then has the flexibility of using almost any computer with the proper software for its base unit 20 since the use of RS-232-C serial ports is so prevalent.

Under the EIA (Electronics Industries Association) RS-232-C standard, binary state 1 (one) signals are transmitted as a voltage between -5 and -15 volts. Binary state 0 (zero) signals are transmitted as a voltage between +5 and +15 volts. In the field unit the binary state 1 is at +4.2 volts and the binary state zero is at 0 volts ("ground"). Thus, the interface unit must be capable of converting the field unit's +4.2 volt transmissions into -5 to -15 volt signals, and must convert 0 volt levels into +5 to +15 volt signals for proper reception by the base unit RS-232-C port. Conversely, the -5 to -15 volt signals from the base unit port must be changed to approximately +4.2 volts, and +5 to +15 volt signals must be changed to 0 volts (ground) for use by the field unit. The base unit presently preferred (Radio Shack Model 100) outputs +/-5 volts on its RS-232-C transmission lines.

Interface unit 22 includes the following primary elements to provide the functions described above: a multi-voltage power supply including a power supply element 400, preferably a CALEX 22-120, a regulator 402, preferably a 7805, a RS-232-C line receiver 410, a RS-232-C line

driver 420, and connectors and cables to interconnect the base 20, interface 22, and field units 24. The power supply converts 120 volts AC input power into +12, -12, and +4.3 volts DC outputs for use by the line driver and receiver circuits. One fourth of a MC1488 Quad Line Driver takes 0 and +4.2 volts DC signals from the field unit's transmitting port (MC146805E2, pin 9, PA5) and converts them to +12 and -12 volts DC signals, respectively, for transmission to the base unit's receiving line (RXR, pin 3). One fourth of a MC1489 quad line receiver takes +5 and -5 volts DC signals from the base unit's transmitting line (TXR, pin 2), and converts them to 0 and +4.3 volts DC signals, respectively, for transmission to the field unit's receiving port (MC146805E2, pin 14, PA0).

The RS-232-C interface standard provides for up to 25 lines for control and data, but this system only requires use of three: line 2, TXR; line 3, RXR; and line 7, GND. Similarly, only three lines are needed between the interface unit and field unit.

The interface unit 22 circuitry does not necessarily need to be housed in a separate cabinet. These electronics could be contained in the field unit except for the disadvantages associated with the increased volume required for the electronics and the additional batteries needed to meet RS-232-C line voltage requirements. The interface electronics could also be contained in the base unit housing, especially since the required voltages are often already available. However, we presently separately house the interface electronics so that

other base units may be used without hardware modifications.

Base Unit Hardware

Referring now to FIGURE 28 there is shown a block diagram of base unit 20.

5 Base unit 20 provides the compliance monitor system user with a means of programming field units with the instructions necessary to control drug delivery and a means by which to retrieve data stored in the field unit at the end
10 of the dosing program. Base unit 20 further provides a means for processing the recovered data and generating analytical reports detailing all system operations.

Base unit 20 is a computer system
15 advantageously combining the following attributes:

1. ROM/RAM memory size sufficient to contain the LOAD-M and READ-M programs with their associated workspaces (approximately 12,500 bytes when written in BASIC) plus
20 its own operating systems.
2. RS-232-C Serial communications interface -- for loading data to and unloading data from the interface/ field units.
3. Interface to a hard copy device --
25 usually a parallel printer port.
4. Display -- internal or external; CRT, LCD, etc. -- for prompting user.
5. Keyboard or other data entry device.
6. Hard copy unit -- usually a dot matrix
30 printer capable of printing both text and graphics.

Other features of the base unit include:

1. A high level programming language (BASIC, FORTRAN, etc.) interpreter for ease of software development and revision.
- 5 2. BASIC interpreter in ROM -- eliminates the need for loading the system from, disk or tape before each operating session.
- 10 3. Sockets for application program ROMs -- eliminates the need for loading the application programs from disk or tape before each operating session; ROM does not require continuous battery backup; software is better protected from pirating.
- 15 4. Additional ROM/RAM memory space beyond the minimal requirement such that application programs for statistical analyses, protocol screening, etc. can reside in, and be run from, this one computer.
- 20 5. An on-board real time clock so that the operator need not repeatedly enter time and date information during field unit load and read operations.
- 25 6. A high level of system component integration -- for minimum space requirement, portability, battery operation, and lower cost.

The preferred embodiment uses a Radio
30 Shack Model 100 portable computer 500 and an Epson RX-80 dot matrix graphics printer 510 to meet the above requirements. The Model 100 integrates all of the required functions, except that of the printer, plus several others into one very compact

and inexpensive unit. It contains 32K bytes of ROM where the BASIC interpreter resides. 32K bytes of RAM are available, part of which may hold the LOAD-M and READ-M application programs. This RAM is backed-up by a NICAD battery which retains the programs in memory indefinitely when the AC adapter is used or for several days when the unit is operated from batteries. Future versions of the base unit will have the application programs stored in a second 32K byte ROM for which there is a socket in the bottom of the computer. The programs could then never be lost due to loss of battery charge. Further, when programs are in ROM, they are stored in machine language or tokenized BASIC, thus affording better software security.

The Model 100's input/output ports include a parallel printer port for sending output to the dot matrix printer and a RS-232-C serial communications port for communicating with the interface/field units and, perhaps, with other computers. The serial port operates at several user-selectable baud rates including the relatively slow 110 baud rate. This rate is still fast enough to provide a convenient data transfer rate while slow enough to allow the use of a battery conserving, slower clock frequency in the field unit.

Other I/O ports available, but not presently used, are a bar code wand input, a cassette recorder interface, and a telephone modem. A bar code wand could be used with future models to take inventories required for drug control. The cassette recorder port provides a means for reloading the application programs into

memory if memory backup power is ever lost. The modem might be used to allow future field and base units to communicate remotely over phone lines.

The Model 100 has an on-board real time clock so that time and date information need be inputted or updated only infrequently.

The display function is provided by an internal 40 character by 8 line liquid crystal dot graphics display. Prompts and data may be presented in any combination of text and graphics.

The typewriter style keyboard includes cursor control and function keys for easy data entry and program selection.

The Epson RX-80 dot matrix graphics printer has both text and graphics print modes and uses 8½ x 11" continuous forms. Data and instructions from the Model 100 are handled by a standard Centronics compatible, 8-bit parallel interface.

Of course, many other computer and peripheral combinations could provide the required base unit functions. The Model 100 and RX-80 units were chosen because they offered the best combination of features and low cost then available. Another method of reducing system cost would be to provide software packages for several common computer systems that meet base unit requirements. The customer then would be able to make use of already existing computer hardware.

Base Unit Load Software

Referring now to FIGURE 29 there is shown a flowchart of the base unit "LOAD-M" software for storing a medication schedule into a field unit

24. A detailed program listing is set forth in Appendix II.

5 The LOAD-M program is selected by moving the main menu cursor over LOAD-M and pressing the "Enter" key. The program starts automatically and prompts the user through all loading operations. Even the most inexperienced operator should be capable of reliable data entry after only minimal training. Proper format checks and escape sequences prevent and correct most erroneous inputs.

10 LOAD-M is selected after field unit 24 has been loaded with dosages and before being given to the patient. The program collects the study and patient identifying data and the dosage schedule and control data through keyboard responses to instructions prompted on the liquid crystal display. This data is loaded into the field unit by way of the interface unit. Finally, a hard copy report of the loaded data is printed.

20 More specifically, operation is as follows:

1. MMS Logo, Copyright Notice, and "Monitor Loading Routine" Displayed.
 2. Data Entry - Identifying and schedule data are entered.
- a. Study ID# - 1 to 6 alphanumeric characters. If more than six characters are entered, only the first six are used. Other formats could be used.
 - 30 b. Patient ID# - 1 to 6 alphanumeric characters. If more than six characters are entered, only the first six are used. Other formats could be used.

- 5 c. Daily dosing schedule - 1 to 4 "on the hour" dosing times. Each selected time must be no earlier than the previous dosing time. Selection is made by moving the cursor over the desired hour and pressing "Enter". Once four times are entered, the program automatically jumps to the next operation. An "entry complete" input is required when less than 4 dosing times are entered.
- 10 d. First Dosage Time - The selected dosage schedule is displayed on the LCD screen and the starting dosage is chosen by moving the cursor over the desired time and pressing "Enter".
- 15 e. Starting Day Offset - If dosage taking is not to begin before the end of the current day, the number of days before dosages are to be taken should be entered. This feature allows the
- 20 monitor system operator to load field units in advance, whenever convenient.
- 25 f. Number of Doses Loaded - Knowing the number of doses loaded allows field unit 24 to stop alarm and display functions after the last dose is delivered.
- 30 g. Monitor Serial # - 1 to 6 alphanumeric characters. If more than six characters are entered, only the first six are used. An "L" in the first position indicates that the field unit being loaded has the computer controlled unlock feature and that the unlock period must be inputted. Other formats could be used.

- 5 g. Unlock Period - The operator chooses one of four unlock periods (2 min., 30 min., 59 min., or "Always") by moving the cursor over the proper label and pressing "Enter". In operation, the field unit will unlock the ejector mechanism before the scheduled dosing time by the amount of time specified by the unlock period. Other periods could be used.
- 10 h. Alarm Start - The operator chooses one of four alarm start periods (2 min., 15 min., 30 min., or "None") by moving the cursor over the proper label and pressing "Enter". In operation, the field unit will start sounding the reminder alarm four times every minute when the actual time is within the alarm start period before the scheduled dosing time. Other periods could be used.
- 15 i. Time/Date Check - The computer will display the time and date as given by its own real time clock. If either time or date is in error, the operator may easily correct them at this time by entering the correct values using the formats shown.
- 20
- 25

30 Note: Data formats other than those shown above (i.e. longer or shorter serial numbers; fewer, more, or different unlock and alarm start periods; different dosage scheduling options; etc.) can be used as long as the field unit has sufficient RAM capacity and is programmed to

interpret a different set of schedule parameters.

3. Field Unit Loading/Testing - Entered data is moved into field unit.

- 5 a. First, LOAD-M disassembles and converts the entered string values into 50 bytes of data suitable for transmission to and use by the field unit.
- 10 b. The operator is then prompted to connect the interface unit (which is connected to the base unit at the RS-232-C port) to the field unit. When the field unit's reset switch is pushed the base unit and field unit begin
- 15 communications. The entire loading operation is automatic and needs no operator intervention. The LOAD-M program signals to the field unit that a load operation is beginning, waits for a
- 20 "Ready" reply, and then sends the 50 bytes of data in a sequence expected by the field unit. After each byte is sent, the base unit checks that the field unit has echoed the proper data
- 25 indicating good data transmission. If a bad echo is received, the data transfer is aborted and restarted.
- 30 c. After loading is complete, the operator is prompted to check alarm and unlock features of the field unit if so desired. By pressing "B" the alarm should sound. By pressing "U" the unlock solenoid should activate.

- d. When loading and testing are complete, LOAD-M prompts the operator to turn off and disconnect the interface unit, and ready the printer.

5 4. Print Permanent Record of the Loading
Operation.

- a. The program proceeds to automatically print a one page record of the loading operation (see sample in Appendix II).
10 All inputted data is repeated and the time and date of loading is recorded. This record then serves to document the loading phase of the monitoring program for use in the patient's, program, and
15 physician's files.

5. Program Exit.

- a. The operator is asked whether there is another field unit to be loaded. If so, the program jumps to the beginning (just
20 after the logo and copyright notice) to restart. If there are no more field units to load, LOAD-M is exited and program control returns to the Model 100 main menu where another program may be
25 selected if desired.

Note: The LOAD-M operations require only approximately two minutes to complete (per field unit).

Base Unit Read Software

- 30 Referring now to FIGURE 30 there is shown a flowchart of the base unit "READ-M" software for

debriefing a field unit 24 and preparing a compliance report. A detailed program listing and a sample compliance report are set forth in Appendix III.

5 The READ-M program is selected by moving the main menu cursor over READ-M and pressing the "Enter" key. The program starts automatically and prompts the user through all unloading operations. Even the most inexperienced operator should be
10 capable of debriefing field units after only minimal training.

 READ-M is selected after the patient returns the field unit at the end of the dosing program. The program unloads from the field unit,
15 by way of the interface unit, the dosage delivery data as well as the previously loaded identification and schedule control data. The data is analyzed, presented on the LCD, and printed on a one or two page report. The format of the LCD and
20 hard copy reports is such that the level of compliance is evident at a glance.

 More specifically, operation is as follows:

- 25 1. MMS Logo, Copyright Notice, and "Monitor Debriefing Routine" are displayed.
2. Unload Field Unit - Stored data is moved into base unit.
 - 30 a. Operator is prompted to connect the interface unit (which is connected to the base unit at the RS-232-C port) to the field unit, turn on the interface unit, and press the field unit's reset switch.
 - 35 b. After the reset switch is pressed, the base unit and field unit begin

communications through the interface unit. The entire unloading operation is automatic and needs no operator intervention. The READ-M program awaits a "Ready" signal from the field unit, then signals that an unload operation is beginning. Having established communications, the field unit sends 131 bytes of data to the base unit. The first 50 bytes are the same data originally stored during the load operation. The 51st byte sent contains the count of dosages taken. The final 80 bytes, arranged as 40 pairs, are compressed representations of the dosage delivery time and date data. If all 40 dosages were not taken, data pairs beyond the dosages taken point contain meaningless data. After each data byte is received by the base unit, it is echoed to the field unit to verify proper data transfer. If the field unit receives a bad echo, it sends an ASCII '?' to the base unit which causes the READ-M program to restart the unload operation.

3. Assemble Identifying and Schedule

Data.

- a. The first 50 bytes received are assembled into the proper string and numeric variables that represent the schedule and identifying data originally loaded into the field unit by the LOAD-M program.

4. Display Compliance Report.

- a. The READ-M program next unpacks the dosage delivery data and presents an analysis of the compliance levels along with the identifying and schedule data on the liquid crystal display. Compliance is shown by plotting the dosage number against the actual dosing time error. The five error levels used are:

- More than 2 hours early
- Less than 2 hours early
- Within plus or minus one hour
- Less than 2 hours late
- More than 2 hours late

An asterisk is plotted at the appropriate error level for each of the dosages taken.

5. Print Hard Copy of the Compliance

20 Report.

- a. The compliance report described in 4 is output to the printer. However, instead of plotting an asterisk, the actual dosing time in hours and minutes is plotted at the appropriate error level for each of the dosages taken. Additionally, if the actual dosing time is not on the proper day, the number of days early or late is printed after the dosing time. The hard copy report will require one or two pages depending upon the number of dosages taken. This record then serves to document the

debriefing phase of the monitoring program for use in the patient's, program, and physician's files.

Note: Other methods of presenting the compliance analysis (e.g. using four hour error bands, statistical analyses, etc.) are equally valid. The READ-M program quickly shows compliance levels "at-a-glance" and assumes that more detailed analyses can be made in other programs.

6. Program Exit.

- a. The operator is asked whether there is another field unit to be unloaded. If so, the program jumps to the beginning (just after the logo and copyright notice) to restart. If there are no other field units to unload, READ-M is exited and program control returns to the Model 100 main menu where another program may be selected if desired.

Note: The READ-M operations require only approximately two minutes to complete (per field unit).

25 Further Enhancements

- Additional base unit software can be provided for patient screening per the drug therapy protocol during the loading operation in medication efficacy studies.

- Additional base unit software can be provided to do statistical analyses of the compliance data for one or more patients.

- By means of a keyboard or card reader
5 one field unit could keep track of dosage delivery to several patients by requiring the entry of access and identifying codes.

- A modem contained within, or attached to, the field unit would allow remote uploading of
10 data to the base unit from the field unit and downloading of new instructions to the field unit from the base unit.

While the invention has been described in connection with what is presently considered to be
15 the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments but on the contrary, is intended to cover various modifications and equivalent arrangements included within
20 the spirit and scope of the appended claims which scope is to be accorded the broadest interpretation so as to encompass all such modifications and equivalent structures.

CONTROLLED DISPENSING DEVICE
FIELD UNIT PROGRAM LISTING

APPENDIX I

MONITOR5.TXT

REV. 07

08.22.84.LEP

5

CLOCKS: 32.768 kHz (F1) INTO 146818 FROM CRYSTAL OSCILLATOR
32.768 kHz (F2) (F1/1) INTO 146805E2 FROM 146818
6553.6 Hz (F3) (F2/5) BUS FREQUENCY

10 BUS CYCLE PERIOD = .000152588 SEC. (1/F3)

FOR 110 BAUD:

TOTAL CYCLES / BIT PERIOD = 60 = 59.57818 = 6553.6/110
(.7% ERROR)

PORT ASSIGNMENTS: PORT A: 0000

15

DDRA : 0004 00 UPON RESET

FC UPON INITIALIZATION

BIT 0 = IN(0) = RS-232C INTO MONITOR (FROM LINE 2, TXR)
MARK(-12v)=1(+4.3v) SPACE(+12v)=0(GND)
SET MODEL 100 FOR 28N1D

20

1 = IN(0) = SPROCKET LOCK STATUS SWITCH

HIGH = LOCKED LOW = UNLOCKED

2 = OUT(1) = DEBUG USE ONLY (GREEN LED - 'MINUTE')

3 = OUT(1) = DEBUG USE ONLY (RED LED-'WAIT'&'DOSAGE')

4 = OUT(1) = SOLENOID - UNLOCK

25

5 = OUT(1) = RS-232C OUT OF MONITOR (TO LINE 3, RXR)
1(+4.3v)=MARK(-12v) 0(GND)=SPACE(+12v)

SET MODEL 100 FOR 28N1D

6 = OUT(1) = MICROSWITCH #2 - DRUG DELIVERED

7 = OUT(1) = MICROSWITCH #1 - DRUG DELIVERED

PORT B: 0001

DDRB : 0005 00 UPON RESET

FF UPON INITIALIZATION

BIT 0 = OUT(1) = LCD DATA, B0

1 = OUT(1) = LCD DATA, B1

2 = OUT(1) = LCD DATA, B2

3 = OUT(1) = LCD DATA, B3

4 = OUT(1) = LCD DIGIT SELECT, DS1

5 = OUT(1) = LCD DIGIT SELECT, DS2

6 = OUT(1) = LCD CHIP SELECTS

7 = OUT(1) = PIEZO ALARM

146818 REGISTERS:

REGISTER A(\$010A) - 00101010 = 2A = 32.768 kHz CRYSTAL

15.625 mSec PI

64 Hz SQW (NOT USED)

BIT 0 - 3 RATE SELECT (0000 = 15.625 mSec PI,

64 Hz SQW)

4 - 6 DIVIDER BITS (010 = 32.768 kHz CRYSTAL)

7 UPDATE IN PROGRESS FLAG (READ ONLY)

20 REGISTER B(\$010B) - 00100110 = 26 = RUN, PIE DISABLED,

AIE ENABLED, UIE DISABLED,

SQWE DISABLED, BINARY, 24,

NO DSE

SET BIT 7(HOLD)(\$A6) DURING TIME INITIALIZE

64

BIT 0 - DAYLIGHT SAVINGS ENABLE (0=DISABLE)

1 - 24/12 HOUR FORMAT (1=24)

2 - DATA MODE (1=BINARY)

3 - SQW ENABLE (0=DISABLE)

5 4 - UPDATE ENDED INTERRUPT ENABLE (0=DISABLE)

5 - ALARM INTERRUPT ENABLE (1=ENABLE)

6 - PERIODIC INTERRUPT ENABLE (0=DISABLE)

7 - SET (1=HOLD 0=RUN)

REGISTER C(010C) - READ ONLY (CLEARED BY A READ)

10 BIT 6 - PERIODIC INTERRUPT FLAG

5 - ALARM INTERRUPT FLAG

0

REGISTER D(010D) - READ ONLY (NOT USED)

146818 RAM: 0100 SECONDS

15 0101 SECONDS ALARM

0102 MINUTES

0103 MINUTES ALARM

0104 HOURS

0105 HOURS ALARM

20 0106 DAY OF WEEK

0107 DATE OF MONTH

0108 MONTH

0109 YEAR

010A REGISTER A

25 010B REGISTER B

010C REGISTER C

010D REGISTER D

(USER RAM) (ALL DATA IS ASCII)

(NUMERIC VALUES ARE REPRESENTED BY ASCII EQUIVALENT)

	010E	D\$(0)	SI\$ LEFT]
	010F	D\$(1)	SI\$]
5	0110	D\$(2)	SI\$]
	0111	D\$(3)	SI\$ } STUDY ID#
	0112	D\$(4)	SI\$]
	0113	D\$(5)	SI\$ RIGHT]
	0114	D\$(6)	PI\$ LEFT]
10	0115	D\$(7)	PI\$]
	0116	D\$(8)	PI\$]
	0117	D\$(9)	PI\$ } PATIENT ID#
	0118	D\$(10)	PI\$]
	0119	D\$(11)	PI\$ RIGHT]
15	011A	D\$(12)	SN, # OF DOSAGES/DAY, 1-4
	011B	D\$(13)	SC(0) SCHEDULED DOSING HOUR (TARGET HOUR) (0-23)
	011C	D\$(14)	SC(1)
	011D	D\$(15)	SC(2)
	011E	D\$(16)	SC(3)
20	011F	D\$(17)	D1, FIRST DOSAGE POINTER, 0-3
	0120	D\$(18)	SN\$ LEFT]
	0121	D\$(19)	SN\$]
	0122	D\$(20)	SN\$]
	0123	D\$(21)	SN\$ } MONITOR SERIAL#
25	0124	D\$(22)	SN\$]
	0125	D\$(23)	SN\$ RIGHT]
	0126	D\$(24)	UP, UNLOCK PERIOD (58,30,01, OR 61)
	0127	D\$(25)	AP, ALARM PERIOD (58,45,30, OR 61)
	0128	D\$(26)	DA\$ LEFT]
30	0129	D\$(27)	DA\$]

012A D\$(28) DA\$]
012B D\$(29) DA\$]
012C D\$(30) DA\$ } LOADING DATE
012D D\$(31) DA\$]
5 012E D\$(32) DA\$]
012F D\$(33) DA\$ RIGHT]
0130 D\$(34) TM\$ LEFT]
0131 D\$(35) TM\$]
0132 D\$(36) TM\$]
10 0133 D\$(37) TM\$]
0134 D\$(38) TM\$ } LOADING TIME
0135 D\$(39) TM\$]
0136 D\$(40) TM\$]
0137 D\$(41) TM\$ RIGHT]
15 0138 D\$(42) STARTING MINUTES (26 GOES TO 27 IN LOAD-M)
0139 D\$(43) STARTING HOURS
013A D\$(44) SD, STARTING DAY OFFSET
013B D\$(45) TD, TOTAL # OF DOSAGES, 1 - 40 (26-27 IN LOAD-M)
013C D\$(46) 0 (NOT USED)
20 013D D\$(47) 0 (NOT USED)
013E D\$(48) 0 (NOT USED)
013F D\$(49) 0 (NOT USED)

146805 RAM MAP:

	0000	PORT A	PORT A DATA REGISTER
	0001	PORT B	PORT B DATA REGISTER
	0002		EXTERNAL MEMORY SPACE
5	0003		EXTERNAL MEMORY SPACE
	0004	DDRA	PORT A DATA DIRECTION REGISTER
	0005	DDRB	PORT B DATA DIRECTION REGISTER
	0006		EXTERNAL MEMORY SPACE
	0007		EXTERNAL MEMORY SPACE
10	0008	TIDATA	TIMER DATA REGISTER
	0009	TCR	TIMER CONTROL REGISTER
			TCR7 - INTERRUPT REQUEST (CLEARED BY RESET)
			TCR6 - INTERRUPT MASK (1=MASKED)
			TCR5 - EXTERNAL CLOCK SOURCE (1=EXTERNAL)
15			TCR4 - EXTERNAL TIMER PIN ENABLED (1=ENABLE)
			TCR3 - PRESCALER RESET TO 0 WITH A 1
			TCR2 - TCR0 - DIVIDE BY FACTOR (000= /1)

0010 ATEMP TEMPORARY STORAGE OF A
TEMP. STORAGE OF DAY OF WEEK DATA
FROM RTC READ

5 0011 CHAR CHARACTER BYTE FOR SEND C
RECEIVED CHARACTER ASSEMBLY BYTE IN REC C
@HOUR2 - 1

0012 COUNT BIT COUNTER FOR SEND C & REC C

0013 XTEMP TEMPORARY STORAGE OF X

0014 @HOUR TARGET HOUR (0-23)

10 0015 NEXTHR NEXT HOUR POINTER, 0-3

0016 DAYCNT ACTUAL DAY COUNTER (# RTC DAY OF WEEK CHANGES)

0017 @DAY TARGET DAY COUNTER (# OF NEXTHR WRAP-AROUNDS)

0018 HOURS ACTUAL HOURS DATA REGISTER - FROM RTC READ

0019 MINUTS ACTUAL MINUTES DATA REGISTER - FROM RTC READ

15 001A DAYWEK DAY OF WEEK REFERENCE

001B @HOUR2 UPCOMING TARGET HOUR

001C DOSTKN D\$(50), # OF DOSES DELIVERED

001D-006D D\$(51)-D\$(131), TIME AND DAY STORAGE
(80 BYTES)

20 006E-007F STACK (17 BYTES)

146805 ROM MAP:

MAIN ROUTINES:

1800 RESET UPON MONITOR RESET BY PUSHBUTTON SWITCH
OR POWER UP

5 1820 RECOGN 'READY', LOAD OR UNLOAD, 'ERROR'

1840 LOAD READS DATA FROM BASE UNIT INTO MONITOR

18A0 START INITIALIZES AND STARTS RTC

1900 UNLOAD SENDS DATA FROM MONITOR TO BASE UNIT

1A00 WAIT POWER DOWN & WAIT FOR INTERRUPT OR RESET

10 1B00 MINUTE TIMER (RTC ALARM) INTERRUPT SERVICE
ROUTINE (1/MIN)

1D00 DOSAGE EXTERNAL INTERRUPT (DOSAGE DELIVERED)
ROUTINE

SUBROUTINES:

5 1E00 SEND C SERIAL OUTPUT TO INTERFACE UNIT
 CHARACTER MUST BE IN REG A BEFORE
 ENTERING ROUTINE
 REG A IS ALTERED
 CHARACTER IS IN 0010 ('ATEMP') AT END
 110 BAUD, START, 8 DATA, NO PARITY, 1 STOP
 SET MODEL 100 FOR 28N1D

10 1E30 DELAY 30 CYCLE DELAY FOR SERIAL COMMUNICATIONS
 ROUTINES
 CALLED BY 'SEND C' AND 'REC C'
 X IS ALTERED IF 'DELAY' NOT USED IN REC C
 OR SEND C

15 1E40 REC C SERIAL INPUT FROM INTERFACE UNIT
 RECEIVED CHARACTER GOES INTO REG A
 REG A IS ALTERED
 110 BAUD, START, 8 DATA, NO PARITY, 1 STOP
 SET MODEL 100 FOR 28N1D

20 1E80 BADCOM BAD COMMUNICATION - SENDS '?' AND WAITS

 1E90 UNLOCK UNLOCK SOLENOID ON FOR 50 mSec (IF LOCKED)

 1EA2 BELL PIEZO ALARM ON FOR 100 mSec/ OFF FOR 500 mSec

 1EC0 ADVTGT TARGET REGISTERS & LCD UPDATE TO NEXT
 DOSING HOUR

SUBROUTINES (continued):

1F20 LCDOUT LOAD A DISPLAY DIGIT

1F30 RTCRED READ RTC HOURS, MINUTES, & DAY OF WEEK

5 1F50 PACK PACK/STORE HR, MIN & RAM DAY DATA INTO 2 BYTES
OF 146805 USER RAM

1F80 DASH PUT DASH IN HOUR DISPLAY

INTERRUPT VECTORS:

10 1FF6-1FF7 TIMER INTERRUPT FROM WAIT - 1800 ('MINUTE')
1FF8-1FF9 TIMER INTERRUPT - 1800 ('MINUTE')
1FFA-1FFB EXTERNAL INTERRUPT - 1D00 ('DOSAGE')
1FFC-1FFD SWI - 1800 ('MINUTE')
1FFE-1FFF RESET - 1800 ('RESET')

 MAIN ROUTINES:

(RESET SWITCH)

(146805 PORT SET-UP)

	1000 1800	RESET	A6FC	LDA	#\$FC	INITIALIZE 146805E2
5	1002 1802		B704	STA	0004	PORT A DDR SET, PA0 & PA1 INPUTS
	1004 1804		A6FF	LDA	#\$FF	
	1006 1806		B705	STA	0005	PORT B DDR SET, ALL OUTPUTS
10	1008 1808		A6E3	LDA	#\$E3	
	100A 180A		B700	STA	0000	PORT A OUTPUTS INACTIVE
	100C 180C		A640	LDA	#\$40	
15	100E 180E		B701	STA	0001	PORT B OUTPUTS TURNED OFF
	1010 1810		CC1820	JMP	RECOGN	

[19]

NOTE: 146818 DOES NOT NEED TO BE INITIALIZED AT THIS POINT
ALTHOUGH NOT KEEPING CORRECT TIME, IT IS PROVIDING
PROPER F2 (32.768 kHz) SIGNAL INTO 146805 FOR
ACCURATE 110 BAUD TIMING

UPON RESET: PIE,AIE,UIE,SQWE ARE CLEARED

IRQF,PF,AF,UF ARE CLEARED

(LOAD/UNLOAD RECOGNITION)

	1020 1820	RECOGN	A652	LDA	#\$52	
	1022 1822		CD1E00	JSR	SEND C	SENDS 'R'(\$52) FOR 'READY'
5	1025 1825		CD1E40	JSR	REC C	WAITING TO RECEIVE 'L' OR 'U'
	1028 1828		A155	CMP	#\$55	CHECK FOR 'U' (UNLOAD)
	102A 182A		2603	BNE	RECOG1	
	102C 182C		CC1900	JMP	UNLOAD	
10	102F 182F	RECOG1	A14C	CMP	#\$4C	CHECK FOR 'L' (LOAD)
	1031 1831		2603	BNE	RECOG2	
	1033 1833		CC1840	JMP	LOAD	
	1036 1836	RECOG2	CC1E80	JMP	BADCOM	TO 'BAD COMMUNICATION' IF NOT 'U', 'L'
15			[25]			

(LOAD DATA FROM BASE UNIT)

	1040 1840	LOAD	A64C	LDA	#\$4C	
	1042 1842		CD1E00	JSR	SEND C	SEND 'L' (LOAD ECHO)
	1045 1845	LOAD1	CD1E40	JSR	REC C	WAITING TO RECEIVE 'C' (CONTINUE)
20	1048 1848		A143	CMP	#\$43	CHECK FOR 'C'
	104A 184A		26F9	BNE	LOAD1	LOOP UNTIL 'C'
	104C 184C		A652	LDA	#\$52	
	104E 184E		CD1E00	JSR	SEND C	SEND 'R' (READY)

(RECEIVE/STORE/ECHO LOOP)

	1051 1851		5F CLR X	
	1052 1852	LOAD2	CD1E40 JSR REC C	WAITING FOR DATA
	1055 1855		D7010E STA X,010E	WRITE DATA INTO RTC
5				RAM STARTING AT 010E
	1058 1858		4F CLR A	
	1059 1859		D6010E LDA X,010E	RELOAD A FROM RTC FOR
				ECHO
	105C 185C		CD1E00 JSR SEND C	ECHO
10	105F 185F		5C INC X	INCREMENT RTC MEMORY
				POINTER
	1060 1860		A332 CPX #\$32	CHECK FOR END OF FILE
				(50 ITEMS)
	1062 1862		26EE BNE LOAD2	LOOP FOR NEXT DATA

15			BELL TEST - SOLENOID TEST)		
	1064 1864	LOAD4	CD1E40 JSR REC C		WAITING FOR 'C' OR 'B'
					OR 'U'
	1067 1867		A143 CMP #\$43		CHECK FOR 'C'
					(COMPLETE)
20	1069 1869		2712 BEQ LOAD3		
	106B 186B		A142 CMP #\$42		CHECK FOR 'B' (BELL)
	106D 186D		2605 BNE LOAD5		
	106F 186F		CD1EA2 JSR BELL		RING BELL
	1072 1872		20F0 BRA LOAD4		
25	1074 1874	LOAD5	A155 CMP #\$55		CHECK FOR 'U' (UNLOCK)
	1076 1876		26EC BNE LOAD4		
	1078 1878		CD1E90 JSR UNLOCK		PULSE UNLOCK SOLENOID
	107B 187B		20E7 BRA LOAD4		

75

```

107D 187D   LOAD3   A646   LDA   #$46
107F 187F           CD1E00 JSR   SEND C SEND 'F' TO
                        ACKNOWLEDGE FINISH
1082 1882           CC18A0 JMP   START
5           [69]
-----
                        (INITIALIZE 146818 RTC)
10A0 18A0   START   A6A6   LDA   #$A6
10A2 18A2           C7010B STA   010B   RTC PUT ON HOLD DURING
                        TIME SET
10 10A5 18A5           4F     CLR   A
10A6 18A6           C70100 STA   0100   SECONDS SET TO 00
10A9 18A9           A63B   LDA   #59
10AB 18AB           C70101 STA   0101   SECONDS ALARM SET FOR
                        59
15 10AE 18AE           A6FF   LDA   #$FF   DONT CARE CODE
10B0 18B0           C70103 STA   0103   MINUTES ALARM SET
10B3 18B3           C70105 STA   0105   HOURS ALARM SET
10B6 18B6           A62A   LDA   #$2A   SET RTC REGISTER A
10B8 18B8           C7010A STA   010A   32.768 kHz,15.625 mSec
20                        PI,64 Hz SQW
10BB 18BB           C60138 LDA   0138   READ STARTING MINUTES
10BE 18BE           C70102 STA   0102   STARTING MINUTES MOVED
                        INTO 0102
10C1 18C1           C60139 LDA   0139   READ STARTING HOURS
25 10C4 18C4           C70104 STA   0104   STARTING HOURS MOVED
                        INTO 0104
10C7 18C7           A607   LDA   #7
10C9 18C9           C70106 STA   0106   DAY OF WEEK SET TO 7
-----

```

(INITIALIZE 146805 RAM REGISTERS)

	10CC 18CC	B71A	STA	DAYWEK	DAY OF WEEK REFERENCE	
					SET TO 7	
	10CE 18CE	C6011F	LDA	011F	D1	
5	10D1 18D1	B715	STA	NEXTHR	FIRST DOSAGE POINTER	
					INTO NEXTHR	
	10D3 18D3	3F16	CLR	DAYCNT		
	10D5 18D5	3C16	INC	DAYCNT	ACTUAL DAY COUNTER SET	
					TO 1	
10	10D7 18D7	C6013A	LDA	013A		
	10DA 18DA	B717	STA	@DAY		
	10DC 18DC	3C17	INC	@DAY	LOAD TARGET DAY WITH	
					OFFSET + 1	
15	10DE 18DE	3F1C	CLR	DOSTKN	CLEAR DOSES TAKEN	
					COUNTER	
	10E0 18E0	1F00	BCLR7	PA7	ENABLE MICROSWITCH #1	

(INITIALIZE @HOUR & @HOUR2 & SET CLOCK)

	10E2 18E2	CD1ECD	JSR	ADVTG1	SET 1st DOSE TIME INTO	
					DISPLAY	

20

(CLEAR DOSAGE MEMORY)

	10E5 18E5	5F	CLR	ACCX		
	10E6 18E6	START1	6F1D	CLR	001D,X	CLEAR 80 BYTES
						STARTING @ 001D
	10E8 18E8	5C	INC	ACCX	PREVENTS ACCIDENTAL	
25					\$1A (26) IN	
	10E9 18E9	A350	CPX	#80	UNUSED BYTES	
	10EB 18EB	26F9	BNE	START1		

(146805 TIMER SETUP)

10ED 18ED	A630	LDA	\$30	SET UP TIMER CONTROL REGISTER
10EF 18EF	B709	STA	TCR	TCR7 - INTERRUPT REQUEST CLEARED
				TCR6 - INTERRUPT MASK CLEARED
				TCR5 - EXTERNAL CLOCK SOURCE
				TCR4 - EXTERNAL TIMER PIN ENAB.
				TCR3 - PRESCALER NOT RESET TO 0
				TCR2 - TCRO DIVIDE BY 1

15

(LET RTC RUN)

10F1 18F1	C6010C	LDA	010C	READING REGISTER C CLEARS ALARM FLAG
10F4 18F4	A626	LDA	#\$26	SET RTC REGISTER B
10F6 18FE	C7010B	STA	010B	RUN, AIE ON, PIE, UIE, SQWE OFF BINARY, 24, NO DSE

10F9 18F9	CC1B00	JMP	MINUTE	GO TO 'MINUTE' TO SET BELL & UNLOCK
-----------	--------	-----	--------	--

[]

(UNLOAD DATA TO BASE UNIT)

(HANDSHAKE COMMUNICATIONS)

```

5      1100 1900  UNLOAD  A655  LDA  $55
      1102 1902          CD1E00 JSR  SEND C  SEND 'U' (UNLOAD
                                ECHO)

      1105 1905  ULOAD1  CD1E40 JSR  REC C  WAITING TO RECEIVE
                                'C' (CONTINUE)
      1108 1908          A143  CMP  43    CHECK FOR 'C'
      110A 190A          26F9  BNE  ULOAD1 LOOP UNTIL 'C'

```

```

10      (146818 USER RAM UNLOAD/ECHO CHECK LOOP)

      110C 190C          5F    CLR  X

      110D 190D  ULOAD2  D6010E LDA  010E,X  MOVE CHARACTER FROM
                                RTC RAM INTO A

      1110 1910          AD12  BSR  ULOAD6

15      1112 1912          5C    INC  X      INCREMENT DATA COUNTER
      1113 1913          A332  CPX  50
      1115 1915          26F6  BNE  ULOAD2 REPEAT LOOP UNTIL
                                50 BYTES

```

(146805 UNLOAD/ECHO CHECK LOOP)

	1117 1917	5F	CLR	X	
	1118 1918	ULOAD4	E61C	LDA	001C,X LOAD DOSAGE DELIVERY DATA
5	111A 191A	AD08	BSR	ULOAD6	SEND DATA & CHECK ECHO
	111C 191C	5C	INC	X	INCREMENT DATA COUNTER
10	111D 191D	A351	CMP	#81	TEST FOR 81 BYTES SENT
	111F 191F	26F7	BNE	ULOAD4	REPEAT LOOP UNTIL 81 BYTES
15	1121 1921	CC1A00	JMP	WAIT	WAIT FOR INTERRUPT OR RESET EXTERNAL INTERRUPTS ENABLED POWER DOWN

(SEND DATA/CHECK ECHO SUBROUTINE)

	1124 1924	ULOAD6	CD1E00	JSR	SEND C
	1127 1927		CD1E40	JSR	REC C WAITING FOR ECHO
20	112A 192A	B110	CMP	0010,A	CHECK FOR PROPER ECHO
	112C 192C	2703	BEQ	ULOAD3	
	112E 192E	CC1E80	JMP	BADCOM	BAD ECHO, GO TO 'BAD COMMUNICATION'
	1131 1931	ULOAD3	81	RTS	

25 [50]

80

(POWER DOWN MODE - WAITING FOR INTERRUPTS)

1200 1A00 WAIT 8F WAIT WAIT FOR INTERRUPT OR
 5 RESET EXTERNAL
 INTERRUPTS ENABLED
 POWER DOWN

[1]

TIMER INTERRUPT

(RTC ALARM - 1/MIN)

(INTERRUPT MASK BIT SET AUTOMATICALLY UPON INTERRUPT)

10

(ALLOW ONLY EXTERNAL INTERRUPTS)

1300 1B00 MINUTE 1C09 BSET6 TCR6 (5) MASK TIMER
 INTERRUPTS
 1302 1B02 9D NOP ()
 1303 1B03 9C RSP () DON'T USE UP
 15 STACK
 1304 1B04 9A CLI (2) ALLOW EXTERNAL
 INTERRUPTS

(12) 1.8 mSec

20

(TIMER INTERRUPT INDICATOR - FOR DEBUG ONLY)

1305 1B05 MINUT1 1400 BSET2 PA2 TURN ON GREEN LED -
 TIMER INT. INDIC.

81

(UPDATE HOURS, MINUTES AND DAY)

	1307 1B07	CD1F30 JSR	RTCRE	ACTUAL HOURS IN 0018	
				('HOURS')	
				ACTUAL MINUTES IN	
5				0019 ('MINUTS')	
				DAY OF WEEK IN 0010	
				('ATEMP')	
	130A 1B0A	B610	LDA	ATEMP	CURRENT DAY OF WEEK
	130C 1B0C	B11A	CMP	DAYWEK	HAS DAY OF WEEK
10					CHANGED?
	130E 1B0E	2704	BEQ	BELLOK	
	1310 1B10	B71A	STA	DAYWEK	UPDATE DAY OF WEEK
					REFERENCE
	1312 1B12	3C16	INC	DAYCNT	UPDATE ACTUAL DAYS
15					COUNT

(ACTUAL VS TARGET TIME TESTS)

	1314 1B14	BELLOK	B617	LDA	@DAY	
	1316 1B16		4C	INC	ACCA	
	1317 1B17		B116	CMP	DAYCNT	IS TD+1 < AD ?
20	1319 1B19		2406	BHS	MINUT2	
						(AD > TD + 1)
	131B 1B1B		CD13C0 JSR	ADVTGT	VERY LATE - ADVANCE	
					TARGET	
25	131E 1B1E		CC1B14 JMP	BELLOK	RESTART	
	1321 1B21	MINUT2	2620	BNE	MINUT3	
						(AD = TD + 1)
	1323 1B23		B618	LDA	HOURS	
	1325 1B25		AB18	ADD	#24	
30	1327 1B27		B111	CMP	0011	IS HOURS + 24 >=
						@HOUR2 - 1

(ACTUAL VS TARGET TIME TESTS, continued)

	1329 1B29		2506 BLO	MINUT4	
	132B 1B2B		CD1EC0 JSR	ADVTGT	VERY LATE - ADVANCE
					TARGET
5	132E 1B2E		CC1B14 JMP	BELLOK	RESTART
	1331 1B31	MINUT4	CD1E90 JSR	UNLOCK	LATE ALL - UNLOCK IF
					LOCKED & RING BELL
	1334 1B34	MINT11	CD1EA2 JSR	BELL	RING BELL FOUR TIMES
	1337 1B37		CD1EA2 JSR	BELL	
10	133A 1B3A		CD1EA2 JSR	BELL	
	133D 1B3D		CD1EA2 JSR	BELL	
	1340 1B40		CC1B95 JMP	MINT15	EXIT
	1343 1B43	MINUT3	B616 LDA	DAYCNT	
	1345 1B45		B117 CMP	@DAY	
15	1347 1B47		252F BLO	MINUT5	
			(ACTUAL DAY = TARGET DAY)		
	1349 1B49		B618 LDA	HOURS	
	134B 1B4B		B111 CMP	0011	IS HOURS < @HOUR2 - 1?
	134D 1B4D		2506 BLO	MINUT6	
20	134F 1B4F		CD1EC0 JSR	ADVTGT	VERY LATE - ADVANCE
					TARGET
	1352 1B52		CC1B14 JMP	BELLOK	RESTART
	1355 1B55	MINUT6	B114 CMP	@HOUR	
	1357 1B57		2503 BLO	MINUT7	
25	1359 1B59		CC1B31 JMP	MINUT4	LATE - UNLOCK & RING
					BELL
	135C 1B5C	MINUT7	4C INC	ACCA	
	135D 1B5D		B114 CMP	@HOUR	DOES HOURS=@HOUR - 1?
	135F 1B5F		2611 BNE	MINUT8	
30			(WITHIN 1 HOUR)		
	1361 1B61	MINT14	B619 LDA	MINUTS	
	1363 1B63		C10126 CMP	0126	CHECK UNLOCK PERIOD
	1366 1B66		2505 BLO	MINUT9	

(ACTUAL VS. TARGET TIME TESTS, continued)

```

1368 1B68          CD1E90 JSR  UNLOCK  UNLOCK IF NECESSARY
                                   (AM >= UP)

136B 1B6B          B619  LDA  MINUTS
5  136D 1B6D  MINUT9 C10127 CMP  0127  CHECK ALARM PERIOD
1370 1B70          2403  BHS  MINT10
1372 1B72  MINUT8  CC1B95 JMP  MINT15  EARLY - EXIT
1375 1B75  MINT10  CC1B34 JMP  MINT11  RING BELL & EXIT
                                   (AM >= AP)
-----

10  1378 1B78  MINUT5 4C    INC  ACCA  DAYCNT + 1
    1379 1B79          B117  CMP  @DAY  DOES AD = TD - 1 ?
    137B 1B7B          2613  BNE  MINT12
                                   (AD = TD -1)
    137D 1B7D          3D14  TST  @HOUR
15  137F 1B7F          2609  BNE  MINT13
                                   (@HOUR = 0)
    1381 1B81          B618  LDA  HOURS
    1383 1B83          A117  CMP  #23
    1385 1B85          2603  BNE  MINT13
20  (AH = 23)
    1387 1B87          CC1B61 JMP  MINT14  GO TO WITHIN 1 HOUR
                                   TESTS
    138A 1B8A  MINT13  B618  LDA  HOURS
    138C 1B8C          B114  CMP  @HOUR
25  138E 1B8E          2208  BHI  MINT16  <24 HOURS EARLY -
                                   EXIT
    1390 1B90  MINT12  CD1F80 JSR  DASH  >24 HOURS EARLY -
                                   DISPLAY DASH
    1393 1B93          2003  BRA  MINT16  EXIT WITHOUT
30  (DISTURBING DASH)
-----

```

(ACTUAL VS TARGET TIME TESTS, continued)

```

1395 1B95  MINT15  CD1EEB JSR  CLKADV  UPDATE CLOCK TO CLEAR
                                OBSOLETE DASH
1398 1B98  MINT16  C6010C LDA  010C    READ RTC REG C TO
5                                CLEAR ALARM FLAG

139B 1B9B          A601  LDA  #$01
139D 1B9D          B708  STA  TIDATA  LOAD TIMER WITH ONE
                                COUNT
139F 1B9F          1F09  BCLR7 TCR7    CLEAR TIMER INTERRUPT
10                                REQUEST
13A1 1BA1          1D09  BCLR6 TCR6    ALLOW TIMER INTERRUPTS

-----
13A3 1BA3          1500  BCLR2 PA2     TURN OFF GREEN LED -
                                TIMER INT. INDIC.

-----

13A5 1BA5          CC1A00 JMP  WAIT    BACK TO 'WAIT'
-----
15  [ ]

```

EXTERNAL INTERRUPT

(DOSAGE TAKEN - ACTIVE MICROSWITCH ACTUATION)

(INTERRUPT MASK BIT SET AUTOMATICALLY UPON INTERRUPT)

(EXTERNAL INTERRUPT INDICATOR - FOR DEBUG ONLY)

```

20  1500 1D00  DOSAGE 1600  BSET3 PA3  (5) LIGHT RED LED -
                                EXT. INT. INDIC.

```

(INTERCHANGE INTERRUPT SWITCH ACTIVATION)

1502 1D02 B600 LDA PORTA (3)
 1504 1D04 A8C0 EOR #\$C0 (2) 1100 0000
 1506 1D06 B700 STA PORTA (4) PA7 & PA6 STATES
 CHANGED

5

(READ/PACK/STORE DATA)

1508 1D08 CD1F30 JSR RTCRD (6) GET CURRENT HOUR,
 MINUTE, DAY DATA
 150B 1D0B 3C1C INC DOSTKN (5) INCREMENT DOSES
 TAKEN COUNTER
 150D 1D0D CD1F50 JSR PACK (6) PACK/STORE DAY &
 TIME DATA

10

(CHECK FOR UNIT EMPTY)

1510 1D10 B61C LDA DOSTKN ()
 1512 1D12 C1013B CMP 013B () TEST AGAINST
 TOTAL # OF
 DOSAGES, TD
 1515 1D15 2508 BLO DOSAG1 ()
 1517 1D17 CD1F80 JSR DASH DISPLAY DASH
 20 151A 1D1A 1E00 BSET7 PA7 MICROSWITCHES
 DEACTIVATED - NO EXT.INT
 151C 1D1C 1C00 BSET6 PA6
 151E 1D1E 8E STOP WAIT FOR RESET -
 POWER DOWN

20

(ADVANCE TARGET REGISTERS & UPDATE DISPLAY)

151F 1D1F DOSAG1 CD1EC0 JSR ADVTGT () ADVANCE TARGETS
 1522 1D22 1700 BCLR3 PA3 () RED LED OFF

25

86

(EXIT TO MINUTE FOR BELL AND UNLOCK CHECK & THEN WAIT)

1524 1D24 CC1B00 JMP MINUTE

[]

5 SUBROUTINES:

(SERIAL OUTPUT CHARACTER MUST BE IN A)

(USES REG A, REG X, 0010, 0011, 0012)

(ALTERS A, RESTORES X, CHARACTER IN 0010)

10 1600 1E00 SEND C BF13 STX XTEMP (4) STORE X FOR LATER
 RESTORATION

 1602 1E02 B710 STA ATEMP (4)

 1604 1E04 B711 STA CHAR (4) STORE CHARACTER
 IN 0010 FOR ECHO
 CHECK & IN 0011
 FOR SENDING

15 1606 1E06 A609 LDA #9 (2) OUTPUT 9 BITS
 (8 + START)

 1608 1E08 B712 STA COUNT (4) BIT COUNTER IN
 0012

20 160A 1E0A 2008 BRA SENDC3 (3) BRANCH TO OUTPUT
 A 0 (START BIT)

 (21)

25 160C 1E0C SENDC2 3611 ROR CHAR (5) MOVE NEXT BIT
 INTO CARRY

 160E 1E0E SENDC1 2404 BCC SENDC3 (3) TEST FOR SET OR
 CLEAR BIT

 1610 1E10 1A00 BSET5 PA5 OUTPUT A 1

 1612 1E12 2004 BRA SENDC4 BRANCH TO DELAY

87

	1614 1E14	SEND3	1800	BCLR5	PA5	(5) OUTPUT A 0
	1616 1E16		2000	BRA	SEND4	(3) EQUALIZE TIMING
	1618 1E18	SEND4	CD1E30	JSR	DELAY	(6) TO TIMING DELAY FOR 110 BAUD
5	161B 1E1B		3A12	DEC	COUNT	(5) DECREMENT BIT COUNTER
	161D 1E1D		26ED	BNE	SEND2	(3) TEST IF ANOTHER BIT TO SEND
10						(60) CYCLES BETWEEN BITS
	161F 1E1F	STOPBT	9D	NOP		(2) 8 CYCLE DELAY
	1620 1E20		9D	NOP		(2)
	1621 1E21		9D	NOP		(2)
15	1622 1E22		9D	NOP		(2)
	1623 1E23		1A00	BSET5	PA5	(5) SEND STOP BIT
	1625 1E25		CD1E30	JSR	DELAY	(6) DELAY FOR THE STOP BIT
	1628 1E28		BE13	LDX	0013	(3) RESTORE X
20	162A 1E2A		81	RTS		(6) RETURN
			[43]			ASSUMES 8 CYCLES TO REENTER SEND C (129 CYCLES BETWEEN CHARACTERS)

25

30 CYCLE (4.58 mSec) DELAY FOR SEND/RECEIVE SUBROUTINES

(ALTERS X UNLESS USED BY SEND C OR REC C)

1630 1E30 DELAY AE03 LDX #03 (2) COUNTER SET TO 3

5 1632 1E32 DELAY1 5A DECK X (3) DECREMENT LOOP
COUNTER

1633 1E33 26FD BNE DELAY1 (3) LOOP

1635 1E35 9D NOP (2) EQUALIZATION

1636 1E36 9D NOP (2) EQUALIZATION

10 1637 1E37 81 RTS (6) RETURN TO SEND C
OR REC C

[8]

(30) $2+3*6+10 = 30$

(SERIAL INPUT CHARACTER GOES INTO A)

15

(ALTERS A, RESTORES X)

1640 1E40 REC C BF13 STX XTEMP STORE REG X FOR LATER
RESTORATION

1642 1E42 A608 LDA #8

1644 1E44 B712 STA COUNT NUMBER OF DATA BITS
TO READ

20

1646 1E46 REC C1 0000FD BRSET REC C1 TESTS FOR HI TO LO
START BIT
TRANSITION ON PA0

	1649	1E49	1/2DLY	AE04	LDX	#04	(2) DELAY 1/2 BIT TIME (30 CYCLES)
	164B	1E4B	DLY1	5A	DECX	X	(3) DECREMENT COUNTER
	164C	1E4C		26FD	BNE	DLY1	(3) LOOP
5	164E	1E4E		9D	NOP		(2) TIMING EQUALIZATION
	164F	1E4F		9D	NOP		(2) " "
							(30)

10

(NOW IN MIDDLE OF START BIT)

	1650	1E50	FALSE	0000F3	BRSET	REC C1	(5) FALSE START BIT TEST
	1653	1E53		9D	NOP		(2) TIMING EQUALIZATION
15	1654	1E54		9D	NOP		(2) " "
	1655	1E55		9D	NOP		(2) " "
	1656	1E56		9D	NOP		(2) " "
	1657	1E57		9D	NOP		(2) " "
20	1658	1E58		2000	BRA	REC C2	(3) " "
							(18)

(MAIN RECEIVE ROUTINE)

	165A 1E5A	REC C2	CD1E30	JSR	DELAY	(6) ONE BIT TIMING DELAY
5	165D 1E5D		9D	NOP		(2) 6 CYCLE EQUALIZATION
	165E 1E5E		9D	NOP		(2)
	165F 1E5F		9D	NOP		(2)
	1660 1E60		010000	BRCLR	REC C3	(5) TEST INPUT (PA0) AND SET C-BIT
10	1663 1E63	REC C3	3611	ROR	CHAR	(5) ASSEMBLE CHARACTER
	1665 1E65		3A12	DEC	COUNT	(5) DECREMENT BIT COUNTER
15	1667 1E67		26F1	BNE	REC C2	(3) TEST FOR MORE BITS TO READ
						(60) CYCLES BETWEEN BITS
20	1669 1E69		CD1E30	JSR	DELAY	WAIT OUT THE 9TH (STOP) BIT
	166C 1E6C		B611	LDA	CHAR	PUT ASSEMBLED BYTE INTO A
25	166E 1E6E		BE13	LDX	0013	RESTORE X
	1670 1E70		81	RTS		RETURN
						[49]

91

(BAD COMMUNICATION - SENDS ASCII 30 AND WAITS)

1680 1E80 BADCOM 9C RSP RESET STACK POINTER
 1681 1E81 A61E LDA #31E ASCII 30
 1683 1E83 CD1E00 JSR SEND C SEND ASCII 30 (BAD
 5 COMMUNICATION)
 1686 1E86 CC1A00 JMP WAIT WAIT FOR RESTART
 (RESET WILL RESET SP
 TO 7F)

[9]

10

(UNLOCK SOLENOID ON FOR 50 mSec)

(ALTERS A, ALTERS X)

(TEST UNLOCK SWITCH)

1690 1E90 UNLOCK 020001 BRSET1UNLCK1 IS SPROCKET LOCKED ?
 15 (PA1 = 1)
 1693 1E93 81 RTS EXIT - ALREADY
 UNLOCKED

20

1694 1E94 UNLCK1 1800 BSET4 PA4 TURN ON UNLOCK
 SOLENOID

1696 1E96 A60B LDA #11 11*4.58=50 mSec
 ON DELAY

25

1698 1E98 UNLCK2 CD1E30 JSR DELAY
 169B 1E9B 4A DEC A
 169C 1E9C 26FA BNE UNLCK2 LOOP

30

169E 1E9E 1900 BCLR4 PA4 TURN OFF UNLOCK
 SOLENOID

16A0 1EA0 81 RTS

[17]

(PIEZO ALARM ON FOR 100 mSec / OFF FOR 500 mSec)

(ALTERS X, ALTERS A)

	16A2	1EA2	BELL	1E01	BSET7 PB7	BELL ON
<hr/>						
5	16A4	1EA4		A610	LDA #16	ON DELAY OF 6.4 * 16
						= 100 mSec
	16A6	1EA6	BELL01	CD1E30	JSR	DELAY
	16A9	1EA9		4A	DEC	A
	16AA	1EAA		26FA	BNE	BELL01
10	<hr/>					
	16AC	1EAC		1F01	BCLR7 PB7	BELL OFF
<hr/>						
	16AE	1EAE		A650	LDA #80	500 mSec OFF DELAY
	16B0	1EB0	BELL02	CD1E30	JSR	DELAY
15	16B3	1EB3		4A	DEC	A
	16B4	1EB4		26FA	BNE	BELL02
<hr/>						
	16B6	1EB6		81	RTS	
20	<hr/>					
				[21]		
<hr/>						

(INCREMENT 'NEXTHR', '@DAY' IF NECESSARY)

(UPDATE '@HOUR' & '@HOUR2' & DISPLAY)

	16C0 1EC0	ADVTGT 3C15	INC	NEXTHR	INCREMENT NEXT HOUR POINTER
5	<hr/>				
	16C2 1EC2	B615	LDA	NEXTHR	
	16C4 1EC4	C1011A	CMP	011A	COMPARE AGAINST SN
	16C7 1EC7	2504	BLO	ADVTG1	
	16C9 1EC9	3F15	CLR	NEXTHR	WRAP NEXT HOUR POINTER TO 0
10	16CB 1ECB	3C17	INC	@DAY	INCREMENT TARGET DAY COUNTER
	16CD 1ECD	ADVTG1 B615	LDX	NEXTHR	
	16CF 1ECF	D6011B	LDA	011B,X	
15	16D2 1ED2	B714	STA	@HOUR	UPDATE TARGET HOUR REGISTER

(DETERMINE UPCOMING TARGET HOUR)

	16D4 1ED4	5C	INC	ACCX	
20	16D5 1ED5	C3011A	CPX	011A	COMPARE AGAINST SN
	16D8 1ED8	2507	BLO	ADVTG2	
	16DA 1EDA	C6011B	LDA	011B	SC(0)
	16DD 1EDD	AB18	ADD	#24	+24 IF NEXT DAY
	16DF 1EDF	2003	BRA	ADVTG3	
25	16E1 1EE1	ADVTG2 D6011B	LDA	011B,X	
	16E4 1EE4	ADVTG3 B71B	STA	@HOUR2	UPDATE UPCOMING TARGET HOUR
	16E6 1EE6	B61B	LDA	@HOUR2	
	16E8 1EE8	4A	DEC	ACCA	
30	16E9 1EE9	B711	STA	0011	@HOUR2 - 1 INTO 'CHAR'

(LCD UPDATE TO NEXT DOSING HOUR)

(AM/PM CHECK)

	16EB 1EEB	CLKADV	B614	LDA	@HOUR	
	16ED 1EED		A10B	CMP	#11	TEST FOR AM OR PM
5	16EF 1EEF		2204	BHI	PM	
	16F1 1EF1		A630	LDA	#\$30	AM
	16F3 1EF3		2002	BRA	CLK1	
	16F5 1EF5	PM	A632	LDA	#\$32	PM
	16F7 1EF7	CLK1	CD1F25	JSR	LCDOUT	DIGIT 1 UPDATED
10						(CONVERT FROM 24 TO 12 HOUR)
	16FA 1EFA		B614	LDA	@HOUR	
	16FC 1EFC		4D	TST	ACCA	
	16FD 1EFD		2604	BNE	CLK2	
	16FF 1EFF		AB0C	ADD	#12	0 CONVERTED TO 12
15	1701 1F01		2006	BRA	CLK3	
	1703 1F03	CLK2	A10C	CMP	#12	
	1705 1F05		2302	BLS	CLK3	
	1707 1F07		A00C	SUB	#12	13-23 CONVERTED TO 1-11
						(HOUR SEPARATED INTO ONES AND TENS DIGITS)
20	1709 1F09	CLK3	A10A	CMP	#10	
	170B 1F0B		250D	BLO	CLK4	
	170D 1F0D		A00A	SUB	#10	
	170F 1F0F		AB10	ADD	#16	DS1=1 DS2=0
	1711 1F11		CD1F25	JSR	LCDOUT	DIGIT 3 LOADED WITH
25						0,1, OR 2
	1714 1F14		A601	LDA	#01	
	1716 1F16		CD1F25	JSR	LCDOUT	DIGIT 4 LOADED WITH 1
	1719 1F19		81	RTS		EXIT
	171A 1F1A	CLK4	AB10	ADD	#16	
30	171C 1F1C		CD1F25	JSR	LCDOUT	DIGIT 3 LOADED WITH
						0-9
	171F 1F1F		A60F	LDA	#\$0F	
	1721 1F21		CD1F25	JSR	LCDOUT	DIGIT 4 BLANKED
	1724 1F24		81	RTS		EXIT
35			[]			

(LOAD DISPLAY DIGIT)

	1725 1F25	LCDOUT	B701	STA	PORT B	DIGIT & DS1, DS2 DATA TO 7211
5	1727 1F27		1D01	BCLR6	PB6	CHIP SELECTS GO LOW (LATCH INPUT)
	1729 1F29		1C01	BSET6	PB6	CHIP SELECTS GO HI (LATCH OUTPUT)
	172B 1F2B		81	RTS		

			[]			

(READ RTC HOURS & MINUTES)

	1730 1F30	RTCRD	C6010C	LDA	010C	(4) READING RTC REG C CLEARS PF BIT
15	1733 1F33	RTCRD1	C6010C	LDA	010C	(4) (4) (4) LOAD REG C FOR TESTING
	1736 1F36		A440	AND	#\$40	(2) (2) (2) LOOKING FOR BIT 6 (PF) HIGH
20	1738 1F38		27F9	BEQ	RTCRD1	(3) (3) (3) LOOP IF PF NOT SET
	173A 1F3A		C60104	LDA	0104	(4) (4) LOAD CURRENT HOURS
	173D 1F3D		B718	STA	HOURS	(4) (4) STORE (000H HHHH) IN 'HOURS'
25	173F 1E3F		C60102	LDA	0102	(4) (4) LOAD CURRENT MINUTES
	1742 1F42		B719	STA	MINUTS	(4) STORE (00MM MMM) IN 'MINUTS'

1744 1F44	C60106	LDA	0106	(4) LOAD DAY OF WEEK
1747 1F47	B710	STA	ATEMP	STORE IN 'ATEMP'
1749 1F49	81	RTS		(6)
<hr/>				
5	[]			()+() = mSec
				MINIMUM VALID
				ACCESS TIME
				REQUIRED
				7.5 mSec (1/2 PI)
10				IS AVAILABLE
<hr/>				
(PACK DATA INTO TWO BYTES & STORE)				
1750 1F50	PACK	3419	LSR	MINUTS (5) DIVIDES MINUTES
				BY 2 (000M MMMM)
1752 1F52	BE1C	LDX	DOSCNT	(3) LOAD X WITH
15				MEMORY POINTER
1754 1F54	58	LSL	X	(3) MULTIPLY MEMORY
				POINTER X2
1755 1F55	B616	LDA	DAYCNT	(3) (00DD DDDD)
1757 1F57	48	LSL	A	(3)
20	1758 1F58	48	LSL	A (3) (DDDD DD00)
	1759 1F59	A4E0	AND	#\$E0 (2) (DDD0 0000)
				DAYS HI
	175B 1F5B	BB19	ADD	MINUTS (3) (DDDM MMMM)
				DAYS HI + MINUTES
25	175D 1F5D	A11A	CMP	#26 (2) CHECK FOR BREAK
				CODE
	175F 1F5F	2602	BNE	PACK1 (3) OK
	1761 1F61	A61F	LDA	#31 (2) CHANGE 26 TO 31
	1763 1F63	PACK1	E71C	STA 001C,X (6) PACKED DATA STORED
30				IN 146805 RAM

	1765 1F65	B616	LDA	DAYCNT	(3) (00DD DDDD)
	1767 1F67	48	LSL	A	(3)
	1768 1F68	48	LSL	A	(3)
	1769 1F69	48	LSL	A	(3)
5	176A 1F6A	48	LSL	A	(3)
	176B 1F6B	48	LSL	A	(3) (DDDD 0000)
					DAYS LO
	176C 1F6C	BB18	ADD	HOURS	(3) (DDDH HHHH)
					DAYS LO + HOURS
10	176E 1F6E	A11A	CMP	#26	(2) CHECK FOR BREAK CODE
	1770 1F70	2602	BNE	PACK2	(3) OK
	1772 1F72	A61F	LDA	#31	(2) CHANGE 26 TO 31
	1774 1F74	PACK2 E71B	STA	001B,X	(6) PACKED DATA STORED IN 146805 RAM

15

1776 1F76	81	RTS	(6)
	[]	() =	mSec

20

(PUT DASH IN HOUR DISPLAY)

	1780 1F80	DASH	A60F	LDA	#\$0F	
	1782 1F82		CD1F25	JSR	LCDOUT	DIGIT 4 BLANKED
	1785 1F85		A61A	LDA	#\$1A	
25	1787 1F87		CD1F25	JSR	LCDOUT	DIGIT 3 LOADED WITH A DASH
	178A 1F8A		A630	LDA	#\$30	
	178C 1F8C		CD1F25	JSR	LCDOUT	DIGIT 1 LOADED WITH AN A
30	178F 1F8F		81	RTS		
			[]			

 IDENTIFYING ASCII

	17E0 1FE0	4D	M
	17E1 1FE1	4D	M
5	17E2 1FE2	53	S
	17E3 1FE3	40	@
	17E4 1FE4	30	0
	17E5 1FE5	38	8
	17E6 1FE6	2F	/
10	17E7 1FE7	32	2
	17E8 1FE8	32	2
	17E9 1FE9	2F	/
	17EA 1FEA	38	8
	17EB 1FEB	34	4

15

 INTERRUPT VECTORS:

	17F6 1FF6	1B00	TIMER INTERRUPT FROM WAIT - 1B00 (`MINUTE')
20	17F8 1FF8	1B00	TIMER INTERRUPT - 1B00 (`MINUTE')
	17FA 1FFA	1D00	EXTERNAL INTERRUPT - 1D00 (`DOSAGE')
25	17FC 1FFC	1B00	SWI - 1B00 (`MINUTE')
	17FE 1FFE	1800	RESET - 1800 (`RESET')

 [10]

30

 []

CONTROLLED DISPENSING DEVICE
"LOAD-M" PROGRAM LISTING

APPENDIX II

```
10 REM          LOAD-M
5 20 REM          10/13/84
30 REM          REV 04
40 CLEAR
50 MAXFILES=2
90 ON ERROR GOTO 430
10 95 REM -----LOGO-----
100 CLS:LINE (10,2)-(228,60),1,B:LINE (12,4)-(226,58),1,B
110 PRINT @47,"MEDICAL MICROSYSTEMS, INC."
120 PRINT @133,"Copyright 1984"
130 PRINT @248,"Monitor Loading Routine"
15 135 PRINT @275,"A4"
140 FOR I=1 TO 1000:NEXT I
145 REM -----ENTER DATA-----
150 CLS:LINE (184,30)-(221,41),1,B
160 PRINT @163,"";:LINE INPUT "ENTER STUDY ID.# (6 Digits)
20      ";SI$
161 LE=LEN(SI$):IF LE>6 THEN SI$=LEFT$(SI$,6)
162 IF LE<6 THEN 164 ELSE 170
164 FOR I=1 TO 6-LE:SI$=" "+SI$:NEXT I
170 CLS:LINE (190,30)-(227,41),1,B
25 180 PRINT @162,"";:LINE INPUT "ENTER PATIENT ID.#
      (6 DIGITS)      ";PI$
181 LF=LEN(PI$):IF LF>6 THEN PI$=LEFT$(PI$,6)
182 IF LF<6 THEN 184 ELSE 185
184 FOR I=1 TO 6-LF:PI$=" "+PI$:NEXT I
30 185 DIM SC(3),TI$(3),D$(49),IN(3)
190 SN=0:CLS:LINE (8,11)-(189,44),1,B
200 LINE (200,19)-(213,36),1,B:LINE(218,19)-(231,36),1,B
210 PRINT @1,"DAILY SCHEDULE SELECTION (1-4 Entries)"
```

100

```
220 PRINT @83,"1 AM 11 1 PM 11"
230 PRINT @123,"212345678901 212345678901"
240 PRINT @154,"X":PRINT @157,"C"
250 PRINT @241,"Move cursor over hour and press 'ENTER'";
5 260 PRINT @286,"Restart - X Complete - C";
270 PRINT @122,"";
280 A$=INPUT$(1)
290 IF ASC(A$)=28 THEN PRINT @(120+POS(0)+1),"";
300 IF ASC(A$)=29 THEN PRINT @(120+POS(0)-1),"";
10 310 IF ASC(A$)<>13 THEN 280
320 IF CSRLIN<>3 THEN 280
330 IF POS(0)=34 THEN 190
340 IF POS(0)=37 THEN 440
350 IF POS(0)>29 OR POS(0)<3 THEN 280
15 360 IF POS(0)>14 AND POS(0)<18 THEN 280
370 IF POS(0)>14 THEN 390
380 SC(SN)=POS(0)-3:LA=SC(SN):IF LA=0 THEN LA=12
385 TI$(SN)=STR$(LA)+" AM":GOTO 393
390 SC(SN)=POS(0)-6:LA=SC(SN)-12:IF LA=0 THEN LA=12
20 392 TI$(SN)=STR$(LA)+" PM"
393 IF SN=0 THEN 395
394 IF SC(SN)<SC(SN-1) THEN 280
395 IF LA<10 THEN TI$(SN)=" "+TI$(SN)
400 IF LA>9 THEN LA=LA-10
25 405 L$=MID$(STR$(LA),2)
410 PRINT @(160+POS(0)),L$;:PRINT @(120+POS(0)),"";
420 SN=SN+1:IF SN=4 THEN 460
425 GOTO 280
430 IF ERR=9 THEN RESUME 190
30 431 CLS:PRINT "ERROR";ERR:END
432 IF ERR=2 THEN RESUME 1200
434 PRINT "ERROR";:FOR I=1 TO 500:NEXT I:RESUME
440 IF SN=0 THEN 190
450 IF SN=1 THEN D1=0:GOTO 620
35 460 CLS:PRINT @8,"SELECT FIRST DOSAGE TIME";
```

```
470 FOR I=0 TO SN-1:PRINT @128+I*8,TI$(I);:NEXT I
480 PRINT @240,"Move box over first dosage & press ENTER";
490 LINE (3,20)-(39,36),1,B:PRINT @80,"";
500 A$=INPUT$(1):L1=POS(0)*6+3:L2=(POS(0)+6)*6+3
5 510 IF ASC(A$)<>28 THEN 550
520 IF (POS(0)-8)/8=SN-1 THEN 500
530 LINE (L1,20)-(L2,36),0,B:LINE(L1+48,20)-(L2+48,36),1,B
540 PRINT @88+POS(0),"";:GOTO 500
550 IF ASC(A$)<>29 THEN 590
10 560 IF POS(0)<9 THEN 500
570 LINE(L1,20)-(L2,36),0,B:LINE(L1-48,20)-(L2-48,36),1,B
580 PRINT @72+POS(0),"";:GOTO 500
590 IF ASC(A$)<>13 THEN 500
600 IF POS(0)=0 THEN 500
15 610 D1=(POS(0)-8)/8
620 CLS:PRINT @162,"";:LINE INPUT "ENTER STARTING DAY OFFSET
      ";SD$
630 SD=VAL(SD$)
640 CLS:PRINT @162,"";:LINE INPUT "ENTER # OF DOSES LOADED
      (1-40) ";TD$
20 650 TD=VAL(TD$)
700 CLS:LINE(172,30)-(209,41),1,B
710 PRINT @166,"";:LINE INPUT "ENTER MONITOR SERIAL # ";SN$
715 LG=LEN(SN$):IF LG>6 THEN SN$=LEFT$(SN$,6)
25 720 IF LG<6 THEN 730 ELSE 800
730 FOR I=1 TO 6-LG:SN$=" "+SN$:NEXT I
800 I=1
801 IF I=7 THEN 805
802 IF MID$(SN$,I,1)=" " THEN I=I+1:GOTO801
30 804 IF MID$(SN$,I,1)="L" THEN 810
805 UP$=" ALWAYS":UP=0:GOTO 1000
810 CLS:PRINT @10,"SELECT UNLOCK PERIOD";
820 PRINT @96," 2 Min.";CHR$(155);
830 PRINT @136," 30 Min.";
35 840 PRINT @176," 59 Min.";
```

```
850 PRINT @217,"Always";
860 PRINT @280,"Move arrow to selection and press
      ENTER";:PRINT @105,"";
870 A$=INPUT$(1)
5 880 IF ASC(A$)<>31 THEN 920
890 IF CSRLIN=5 THEN 870
900 GOSUB 910:PRINT @(CSRLIN+1)*40+24,CHR$(155);:GOTO 870
910 LINE (144,16)-(149,48),0,BF:RETURN
920 IF ASC(A$)<>30 THEN 950
10 930 IF CSRLIN=2 THEN 870
940 GOSUB 910:PRINT @(CSRLIN-1)*40+24,CHR$(155);:GOTO 870
950 IF ASC(A$)<>13 THEN 870
960 UP=CSRLIN-1
970 ON UP GOTO 972,974,976,978
15 972 UP$=" 2 Min.":UP=58:GOTO 1000
974 UP$=" 30 Min.":UP=30:GOTO 1000
976 UP$=" 59 Min.":UP=1:GOTO 1000
978 UP$=" ALWAYS":UP=61
1000 CLS:PRINT @11,"SELECT ALARM START";
20 1010 PRINT @97," 2 Min.":CHR$(155);
1020 PRINT @137,"15 Min.";
1030 PRINT @177,"30 Min.";
1040 PRINT @219,"NONE";
1050 PRINT @280,"Move arrow to selection and press
25      ENTER";:PRINT @105,"";
1060 A$=INPUT$(1)
1070 IF ASC(A$)<>31 THEN 1100
1080 IF CSRLIN=5 THEN 1060
1090 GOSUB 910:PRINT @(CSRLIN+1)*40+24,CHR$(155);:GOTO 1060
30 1100 IF ASC(A$)<>30 THEN 1130
1110 IF CSRLIN=2 THEN 1060
1120 GOSUB 910:PRINT @(CSRLIN-1)*40+24,CHR$(155);:GOTO 1060
1130 IF ASC(A$)<>13 THEN 1060
1140 AP=CSRLIN-1
35 1150 ON AP GOTO 1160,1170,1180,1190
```

```
1160 AP$=" 2 Min.":AP=58:GOTO 1200
1170 AP$="15 Min.":AP=45:GOTO 1200
1180 AP$="30 Min.":AP=30:GOTO 1200
1190 AP$=" NONE":AP=61
5 1200 CLS:PRINT @48,"DATE IS: ";DATE$;
1210 PRINT @128,"TIME IS: ";TIME$;
1220 PRINT @205,"If correct press 'C'";
1230 PRINT @245,"If incorrect press 'I'";:PRINT @230,"";
1240 A$=INPUT$(1)
10 1250 IF ASC(A$)=67 THEN 1255 ELSE 1260
1255 DA$=DATE$:TM$=TIME$:GOTO 1400
1260 IF ASC(A$)<>73 THEN 1240
1270 LINE(0,32)-(239,63),0,BF
1280 PRINT @201,"Enter correct date using format shown";:PRINT
15 @70,"";
1290 LINE INPUT DA$
1300 LINE(0,32)-(239,63),0,BF
1310 PRINT @201,"Enter correct time using format shown";:PRINT
@150,"";
20 1320 LINE INPUT TM$
1330 DATE$=DA$:TIME$=TM$:GOTO 1200
1400 FOR I=1 TO 6:D$(I-1)=MID$(SI$,I,1):NEXT I
1410 FOR I=1 TO 6:D$(I+5)=MID$(PI$,I,1):NEXT I
1420 D$(12)=CHR$(SN):FOR I=1 TO 4:D$(I+12)=CHR$(SC(I-1)):NEXT
25 I
1430 D$(17)=CHR$(D1)
1440 FOR I=1 TO 6:D$(I+17)=MID$(SN$,I,1):NEXT I
1450 D$(24)=CHR$(UP)
1460 D$(25)=CHR$(AP)
30 1470 FOR I=1 TO 8:D$(I+25)=MID$(DA$,I,1):NEXT I
1480 FOR I=1 TO 8:D$(I+33)=MID$(TM$,I,1):NEXT I
1490 D$(42)=CHR$(VAL(MID$(TM$,4,2)))
1492 IF ASC(D$(42))=26 THEN D$(42)=CHR$(27)
1495 D$(43)=CHR$(VAL(LEFT$(TM$,2)))
35 1496 D$(44)=CHR$(SD)
```

```
1497 D$(45)=CHR$(TD)
1498 IF ASC(D$(45))=26 THEN D$(45)=CHR$(27)
1508 FOR I=1 TO 4:D$(45+I)=CHR$(0):NEXT I
1509 REM -----LOAD FIELD UNIT-----
5 1510 OPEN "COM:28N1D" FOR INPUT AS 1
1520 OPEN "COM:28N1D" FOR OUTPUT AS 2
1530 CLS:PRINT @41,"Verify that Monitor has fresh battery";
1540 PRINT @123,"Connect Interface Unit to Monitor";
1550 PRINT @169,"Turn On Interface Unit";
10 1560 PRINT @247,"Press Monitor Reset Switch";
1600 B$=INPUT$(1,1)
1610 IF B$<>"R" THEN 1620 ELSE 1650
1620 CLS:PRINT @91,"BAD COMMUNICATION";
1630 PRINT @175,"RESTARTING";
15 1640 FOR I=1 TO 500: NEXT I:GOTO 1530
1650 CLS:PRINT @0,"Communications Established";
1700 PRINT #2,"L";:B$=INPUT$(1,1):IF B$<>"L" THEN 1620
1710 PRINT @80,"Monitor Verifies Load Mode";
1800 PRINT #2,"C";:B$=INPUT$(1,1):IF B$<>"R" THEN 1620
20 1810 PRINT @160,"Loading Data";
1820 FOR I=0 TO 49:T$=D$(I):PRINT @176,I+1;:PRINT
    #2,T$;:E$=INPUT$(1,1)
1830 IF E$<>T$ THEN 2445
1835 NEXT I
25 1840 PRINT @240,"Data Transmission Complete";
1850 FOR I=1 TO 500:NEXT I
1860 CLS:PRINT @7,"Press key 'B' to test alarm";
1870 PRINT @89,"Press key 'U' to unlock";
1900 PRINT @161,"Press Key 'C' When Tests Are Complete";
30 1920 PRINT @260,"";:A$=INPUT$(1):IF A$="Y" THEN 1990
1922 IF A$="B" THEN PRINT#2,"B";:GOTO 1920
1924 IF A$="U" THEN PRINT#2,"U";:GOTO 1920
1930 IF A$<>"C" THEN 1920
1990 PRINT #2,"C";
35 2000 B$=INPUT$(1,1):IF B$<>"F" THEN 1620
```

```
2005 REM -----PRINT RECORD-----
2010 CLS:PRINT @46,"Monitor Loading Is Complete";
2020 PRINT @121,"Turn off and disconnect Interface Unit";
2030 PRINT @203,"Printer On?, Align Top, Press 'P'";
5 2040 PRINT @237,"";:A$=INPUT$(1)
2050 IF A$<>"P" THEN 2040
2060 PRINT @292,"Printing Record";
2100 LPRINT:LPRINT
2105 LPRINT TAB(27);"MONITOR LOAD RECORD"
10 2107 LPRINT:LPRINT
2110 LPRINT "Study I.D.#";TAB(65);SI$
2120 LPRINT:LPRINT
2130 LPRINT "Patient I.D.#";TAB(65);PI$
2140 LPRINT:LPRINT
15 2150 LPRINT STRING$(71,"-")
2160 LPRINT:LPRINT
2170 LPRINT "Delivery Schedule:";TAB(65);TI$(0)
2180 IF SN>1 THEN LPRINT:LPRINT TAB(65);TI$(1) ELSE 2210
2190 IF SN>2 THEN LPRINT:LPRINT TAB(65);TI$(2) ELSE 2210
20 2200 IF SN>3 THEN LPRINT:LPRINT TAB(65);TI$(3)
2210 LPRINT:LPRINT
2220 LPRINT "      First Dosage:";TAB(65);TI$(D1)
2230 LPRINT:LPRINT
2234 LPRINT "      Start Offset:";TAB(69);SD
25 2236 LPRINT:LPRINT
2237 LPRINT "      Doses Loaded:";TAB(68);TD
2238 LPRINT:LPRINT
2240 LPRINT STRING$(71,"-")
2250 LPRINT:LPRINT
30 2260 LPRINT "Monitor Serial #";TAB(65);SN$
2270 LPRINT:LPRINT
2280 LPRINT "      Unlock Period:";TAB(63);UP$
2290 LPRINT:LPRINT
2300 LPRINT "      Alarm Start:";TAB(64);AP$
35 2310 LPRINT:LPRINT
```



```
2320 LPRINT "Date Monitor Loaded: ";TAB(63);DA$
2330 LPRINT:LPRINT
2340 LPRINT "Time Monitor Loaded: ";TAB(63);TM$
2350 LPRINT CHR$(12):LPRINT CHR$(12)
5 2360 REM -----EXIT-----
2400 CLS:PRINT @166,"Load Another Unit? (Y or N)";
2410 PRINT @195,"";:A$=INPUT$(1)
2420 IF A$="Y" THEN CLEAR:GOTO 150
2430 IF A$<>"N" THEN 2410
10 2440 CLEAR:MENU
```

CONTROLLED DISPENSING DEVICE
 "READ-M" PROGRAM LISTING

APPENDIX III

```

10  REM      READ-M
5   20  REM      10/13/84
    30  REM      REV 05
    100  CLS:LINE (10,2)-(228,60),1,B:LINE (12,4)-(226,58),1,B
    110  PRINT @47,"MEDICAL MICROSYSTEMS, INC."
    120  PRINT @133,"Copyright 1984"
10  130  PRINT @247,"Monitor Debriefing Routine"
    135  PRINT @275, "A4"
    140  FOR I=1 TO 1000:NEXT I
    150  CLOSE:CLEAR
    200  MAXFILES=2
15  205  DIM D$(134),SC(3),SC$(3),IN(3)
    210  OPEN "COM:28N1D" FOR INPUT AS 1
    220  OPEN "COM:28N1D" FOR OUTPUT AS 2
    230  REM -----UNLOAD-----
    300  CLS:PRINT @83,"Connect Interface Unit to Monitor";
20  310  PRINT @169,"Turn ON Interface Unit";
    320  PRINT @247,"Press Monitor Reset Switch";
    400  B$=INPUT$(1,1)
    410  IF B$<>"R" THEN 420 ELSE 450
    420  CLS:PRINT @91,"BAD COMMUNICATION";
25  430  PRINT @175,"RESTARTING";
    440  FOR I=1 TO 500:NEXT I:GOTO 150
    450  CLS:PRINT @0,"Communications Established";
    460  PRINT #2,"U";:B$=INPUT$(1,1):IF B$<>"U" THEN 420
    470  PRINT @80,"Monitor Verifies Unload Mode";
30  480  PRINT #2,"C";:PRINT @160,"Unloading Data";
    485  ON ERROR GOTO 2000
    490  FOR I=1 TO 131:R$=INPUT$(1,1)
    495  D$(I-1)=R$

```

```
496 IF I=25 OR I=26 OR I=43 OR I=46 THEN 510
500 IF ASC(R$)=30 THEN 420
510 PRINT @176,I;:PRINT #2,R$;:NEXT I
530 PRINT @240,"Data Transmission Complete"
5 540 FOR I=1 TO 500:NEXT I
600 CLS:PRINT @45,"Monitor Unloading is Complete";
610 PRINT @121,"Turn OFF and disconnect Interface Unit";
620 PRINT @203,"Printer ON?, Align Top, Press 'P'";
630 PRINT @237,"";:A$=INPUT$(1)
10 639 IF A$<>"P" THEN 630
640 PRINT @295,"Computing";
641 REM -----ASSEMBLE IDENTIFYING DATA-----
642 SI$=D$(0)+D$(1)+D$(2)+D$(3)+D$(4)+D$(5)
644 PI$=D$(6)+D$(7)+D$(8)+D$(9)+D$(10)+D$(11)
15 646 SN=ASC(D$(12))
648 SC(0)=ASC(D$(13)):SC(1)=ASC(D$(14)):SC(2)=ASC(D$(15)):
      SC(3)=ASC(D$(16))
650 DI=ASC(D$(17))
651 SD=ASC(D$(44)):DT=ASC(D$(45))
20 652 SN$=D$(18)+D$(19)+D$(20)+D$(21)+D$(22)+D$(23)
654 UP=ASC(D$(24)):AP=ASC(D$(25))
656 DA$=D$(26)+D$(27)+D$(28)+D$(29)+D$(30)+D$(31)
      +D$(32)+D$(33)
25 658 TM$=D$(34)+D$(35)+D$(36)+D$(37)+D$(38)+D$(39)
      +D$(40)+D$(41)
660 CT=ASC(D$(50)):IF CT>40 THEN CT=40
661 ON SN GOTO 662,663,664,665
662 IN(0)=24:GOTO 670
663 IN(0)=SC(1)-SC(0):IN(1)=SC(0)+24-SC(1):GOTO 670
30 664 IN(0)=SC(1)-SC(0):IN(1)=SC(2)-SC(1):IN(2)=SC(0)
      +24-SC(2):GOTO 670
665 IN(0)=SC(1)-SC(0):IN(1)=SC(2)-SC(1):IN(2)=
      SC(3)-SC(2):IN(3)=SC(0)+24-SC(3)
670 IF AP=58 THEN AP$="T-2 Minutes"
35 672 IF AP=45 THEN AP$="T-15 Minutes"
```

```
674 IF AP=30 THEN AP$="T-30 Minutes"
676 IF AP=61 THEN AP$="No Alarm"
680 IF UP=58 THEN UP$="T-2 Minutes"
682 IF UP=30 THEN UP$="T-30 Minutes"
5 684 IF UP=1 THEN UP$="T-59 Minutes"
686 IF UP=61 THEN UP$="Always Unlocked"
690 FOR I=1 TO 4
692 IF SC(I-1)<10 THEN SC$(I-1)="0"+RIGHT$
    (STR$(SC(I-1)),1)+"00":GOTO 696
10 694 SC$(I-1)=RIGHT$(STR$(SC(I-1)),2)+"00"
696 NEXT I
698 D1$=SC$(D1)
699 REM -----LCD REPORT-----
700 CLS:PRINT @2,"STUDY ID#:";SI$;
15 720 PRINT @21,"LOAD:";DA$;
735 PRINT " ";LEFT$(TM$,5);
740 PRINT @40,"PATIENT ID#:";PI$;
760 PRINT @59,"UNLOAD:";DATE$;" ";LEFT$(TIME$,5);
770 PRINT @91,"SCH: ";
20 780 FOR I=1 TO SN:PRINT " ";SC$(I-1);:NEXT I
920 LINE (0,24)-(239,63),1,B
930 LINE (0,43)-(239,43)
940 PRINT @200,"";
1000 J=51:K=D1:TT=((SD+1)*24+SC(D1))*60
25 1010 FOR I=1 TO CT
1030 GOSUB 1720
1040 IF TB<>6 THEN 1200
1050 PRINT @200+POS(0),"M";
1060 K=K+1:GOSUB 1220:TT=T1:GOSUB 1745:GOTO 1040
30 1200 PRINT @200+POS(0)+(TB-3)*40,"*";
1210 J=J+2:K=K+1:GOSUB 1220:TT=T1:GOTO 1230
1220 IF K=SN THEN K=0:Z=POS(0):LINE(Z*6-1,24)-(Z*6-1,63):
    PRINT @200+Z,"";
1225 RETURN
35 1230 NEXT I
```

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```

1240 REM -----HARD COPY REPORT-----
1300 LPRINT:LPRINT
1310 LPRINT TAB(19);"COMPLIANCE MONITOR DEBRIEFING REPORT"
1320 LPRINT:LPRINT "Study I.D.#";TAB(65);SI$
5 1330 LPRINT "Patient I.D.#";TAB(65);PI$
1340 GOSUB 1345:GOTO 1350
1345 FOR I=1 TO 71:LPRINT "-";:NEXT I:LPRINT:RETURN
1350 LPRINT "Monitor Serial #";TAB(65);SN$
1360 LPRINT "Loaded on: ";DA$;" @ ";TM$
10 1370 LPRINT "Unloaded on: ";DATE$;" @ ";TIME$
1380 GOSUB 1345
1390 LPRINT "Dosage Schedule:";
1400 FOR I=1 TO SN:LPRINT " ";SC$(I-1);:NEXT I
1410 LPRINT:LPRINT "First Dosage: ";D1$
15 1415 LPRINT "Start Day Offset: ";SD
1417 LPRINT "Doses Loaded: ";DT
1420 LPRINT "Unlock Period: ";UP$
1430 LPRINT "Alarm Period: ";AP$
1440 GOSUB 1345
20 1500 LPRINT:LPRINT "Compliance Profile:"
1510 LPRINT TAB(12);:FOR I=1 TO 59:LPRINT "-";:NEXT I:LPRINT
1520 LPRINT TAB(12);CHR$(124);">2Hr Early
      <2Hr Early +-1 Hour <2Hr Late
      >2Hr Late";CHR$(124)
25 1530 GOSUB 1345
1600 J=51:K=D1:TT=((SD+1)*24+SC(D1))*60
1602 FOR I=1 TO CT
1604 GOSUB 1720
1606 IF TB<>6 THEN 1610
30 1608 GOSUB 1630:GOSUB 1800:K=K+1:GOSUB 1820:TT=TT+1:
      GOSUB 1745: GOTO 1606
1610 GOSUB 1630:GOSUB 1800:GOTO 1810
1620 REM -----TIME LABEL-----
1630 TA$=SC$(K)
35 1635 IF TB=6 THEN TI$="MISSED":TB=3:RETURN

```

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```
1640 IF AH<10 THEN H$="0"+RIGHT$(STR$(AH),1):GOTO 1660
1650 H$=RIGHT$(STR$(AH),2)
1660 IF AM<10 THEN M$="0"+RIGHT$(STR$(AM),1):GOTO 1680
1670 M$=RIGHT$(STR$(AM),2)
5 1680 TI$=H$+M$
1685 DY=AD-INT(TT/1440)
1690 IF DY=0 THEN 1715
1700 IF DY<0 THEN TI$=TI$+"-"+MID$(STR$(ABS(DY)),2):GOTO 1715
1710 TI$=TI$+" "+MID$(STR$(ABS(DY)),2)
10 1715 RETURN
1717 REM -----UNPACK DATA & ERROR CALC-----
1720 B1=ASC(D$(J)):IF B1=31 THEN B1=26
1721 B2=ASC(D$(J+1)):IF B2=31 THEN B2=26
1722 B3=B1:GOSUB 1726:AH=B3
15 1724 B3=B2:GOSUB 1726:AM=B3*2:GOTO 1734
1726 IF B3>127 THEN B3=B3-128
1728 IF B3>63 THEN B3=B3-64
1730 IF B3>31 THEN B3=B3-32
1732 RETURN
20 1734 AD=0:B3=B2
1736 IF B3>127 THEN AD=AD+32:B3=B3-128
1737 IF B3>63 THEN AD=AD+16:B3=B3-64
1738 IF B3>31 THEN AD=AD+8
1739 B3=B1
25 1740 IF B3>127 THEN AD=AD+4:B3=B3-128
1742 IF B3>63 THEN AD=AD+2:B3=B3-64
1744 IF B3>31 THEN AD=AD+1
1745 T1=TT+IN(K)*60:R2=((AD*24+AH)*60+AM)-T1
1746 IF R2>-61 THEN TB=6:RETURN
30 1747 ER=((AD*24+AH)*60+AM)-TT
1750 IF ER>120 THEN TB=5:GOTO 1790
1760 IF ER>60 THEN TB=4:GOTO 1790
1770 IF ER>-61 THEN TB=3:GOTO 1790
1780 IF ER>-121 THEN TB=2:GOTO 1790
35 1785 TB=1
```

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```
1790 RETURN
1795 REM -----PRINT LOCATION-----
1800 LPRINT CHR$(124);RIGHT$(STR$(I),2);CHR$(124);" ";TA$;"
      ";CHR$(124);TAB(3+TB*12);TI$;TAB(70);CHR$(124)
5 1805 RETURN
1810 J=J+2:K=K+1:GOSUB 1820:TT=T1:GOTO 1825
1820 IF K=SN THEN K=0:Z1=I:GOSUB 1345:I=Z1
1822 RETURN
1825 NEXT I
10 1826 REM -----EXIT-----
1830 GOSUB 1345:LPRINT CHR$(12):LPRINT CHR$(12)
1900 CLS:PRINT @165,"Unload Another Unit? (Y or N)";
1910 PRINT @195,"";:A$=INPUT$(1)
1920 IF A$="Y" THEN CLEAR:GOTO 150
15 1930 IF A$<>"N" THEN 1910
1940 CLEAR:MENU
2000 IF ERR = 54 THEN 2020
2005 IF ERR=5 THEN 1240
2010 PRINT ERR:PRINT ERL:STOP
20 2020 CLOSE 1: OPEN "COM:28NID" FOR INPUT AS 1
2025 PRINT "EOF"
2030 RESUME NEXT
```

WHAT IS CLAIMED IS:

1. A dispensing device, comprising:
a storage compartment;
a sleeved strip having a plurality of
5 containers mounted thereon for maintaining a
predetermined order of said containers, said
sleeved strip and containings being stored within
said storage compartment;
dispensing means for dispensing, upon
10 each actuation thereof, one container, said
dispensing means including an ejector element
mounted for rotation about a longitudinal axis
thereof and having container conforming
depressions around its periphery, said depressions
15 being shaped so as to engage and convey individual
containers arranged in said storage compartment in
their order along said sleeved strip; said ejector
element, when rotated through a predetermined
angle, causing one container to be dispensed and
20 the next container in sequence along said sleeve
to be moved into a position ready to be dispensed
upon the next ejector rotation; and means for
actuating said dispensing means.
2. A device according to claim 1 wherein
25 said storage compartment includes a partition
defining a passageway in which said sleeve and
containers are stored.
3. A device according to claim 2 wherein
said passageway has a width that is less than two
30 container diameters.

4. A device according to claim 1 wherein
said ejector element has substantially a cross-
sectional form of a square with semicircular
depressions in each side of the square for
5 engaging cylindrical-shaped containers.

5. A device according to claim 1 wherein
said dispensing means further includes means for
preventing rotation of the ejector element in a
direction opposite to that of rotation to dispense
10 a container.

6. A device according to claim 1 wherein
said dispensing means further includes a stop
arrangement, operable in set and reset positions,
that prevents after each container is dispensed,
15 further dispensing action until the stop mechanism
is reset.

7. A device according to claim 6 further
including means for resetting said stop mechanism
by means of linkages accessible to a user.

20 8. A device according to claim 6 wherein
the stop mechanism includes latching means for
preventing movement of the stop mechanism out of
its set or reset positions.

9. A device according to claim 1 wherein
25 said sleeved strip is adapted so that after it is
loaded with containers, it can be folded into said
storage compartment back and forth across a
passageway thereof such that containers earlier in
said predetermined order are nearer the dispensing
30 means than containers later in the order.

10. A dispensing device, comprising:
a storage compartment for storing a plurality of containers to be dispensed one at a time in predetermined order;

5 means, upon an actuation thereof, for dispensing a container from said storage compartment;

means for storing a dispensing schedule specifying when a dispensing operation can be carried out by said dispensing means;

10 means for alerting a user as to scheduled dispensing times;

means for modifying a schedule stored in said storage means in response to dispensing operations of said dispensing means; and

15 means for inhibiting operation of said dispensing means other than at time specified by said schedule, as modified.

20 11. A dispensing device according to claim 10 wherein said alerting means comprises an audible alarm.

25 12. A dispensing device according to claim 10 wherein said alerting means comprises a visual indicator.

13. A dispensing device, comprising:
storage means for storing a plurality of individual containers;

30 dispensing means for dispensing one container at a time from said storage means, each container being dispensed by executing an individual dispensing operation;

sequencing means for maintaining a predetermined order among the individual containers so that the individual containers are dispensed in said predetermined order by said
5 dispensing means, said sequencing means also including means for providing a predetermined spacing relationship between containers so that they can be engaged by the dispensing means;
electronic memory means for storing data
10 including instructions for operating the device;
electronic time keeping means for providing time information;
electronic logic means for interpreting and executing said instructions;
15 means for supplying electrical power to the time keeping means, logic means and memory means; and
a housing containing said storage means, dispensing means, sequencing means, memory means,
20 time keeping means, logic means, and power supplying means.

14. A device according to claim 13 further including means for sensing and signalling for said logic means, each completed dispensing
25 operation of said dispensing means.

15. A device according to claim 13 wherein said storage means includes a substantially 'U' shaped partition defining a passageway.

30 16. A device according to claim 13 wherein said storage means includes a passageway having a width less than two container diameters.

17. A device according to claim 13 wherein said dispensing means comprises: an ejector element mounted for rotation about a longitudinal axis thereof and having container
5 conforming depressions around its periphery, said depressions being shaped so as to engage and convey individual containers arranged in said storage means in said predetermined order; said ejector element, when rotated through a
10 predetermined angle, causing one container to be dispensed and the next container in sequence to be moved into a position ready to be dispensed upon the next ejector rotation.

18. A device according to claim 17
15 wherein said ejector element has substantially a cross-sectional form of a square with semicircular depressions in each side of the square for engaging cylindrical-shaped containers.

19. A device according to claim 17
20 wherein said dispensing means further includes reverse rotation preventing means for preventing potentially harmful rotation of the ejector element in the direction opposite that used to dispense a container.

20. A device according to claim 19
25 wherein operation of said reverse rotation preventing means, through a common mechanism, simultaneously produces a completed dispensing operation signal.

21. A device according to claim 13 wherein said dispensing means includes a stop arrangement, operable in set and reset positions, that prevents, after each container is dispensed, further dispensing action until the stop mechanism is reset.

22. A device according to claim 21 further including means for resetting said stop mechanism by means of linkages accessible to a user.

23. A device according to claim 21 further including a solenoid and linkages for resetting said stop mechanism under control of said electronic logic means in accordance with said stored instructions thereby controlling the operator's ability to dispense containers, according to said instructions.

24. A device according to claim 23 further comprising a power source separate from said power supplying means for powering the solenoid.

25. A device according to claim 21 wherein the stop mechanism includes latching means for preventing movement of the stop mechanism out of its set or reset positions except as provided for by said instructions.

26. A device according to claim 13 further comprising audible indicating means, controlled by said logic means, for alerting a user as to when a container should be dispensed

according to a predetermined schedule defined by said instructions.

27. A device according to claim 26 wherein said audible indicating means comprises a piezoelectric alarm.

28. A device according to claim 13 further comprising visual indicating means, controlled by said logic means, for prompting a user as to when a container should be dispensed according to a predetermined schedule defined by said instructions.

29. A device according to claim 28 wherein said visual indicating means comprises a liquid crystal display.

30. A device according to claim 13 wherein said sequencing means comprises a thin, flexible strip with regularly spaced sleeves for holding individual containers, one in each sleeve, in a predetermined order.

31. A device according to claim 30 wherein said thin, flexible strip is adapted so that after it is loaded with containers, it can be folded into said storage means back and forth across a passageway thereof such that the containers may be dispensed by the dispensing means in said predetermined order.

32. A device according to claim 14 further comprising second memory means for storing

data, including times of actual dispensing of containers.

33. A device according to claim 32 further comprising communication means for
5 transmitting said data from the device.

34. A device according to claim 13 further comprising communicating means for receiving all or part of said instructions and storing them in said memory means.

10 35. A device according to claim 14 wherein said sensing and signalling means comprises electrical switches activated by actuators following cams of the dispensing means.

36. A device according to claim 13
15 wherein the means for supplying electrical power comprises a battery.

37. A device according to claim 13 wherein said storage means is in a portion of said housing that is separable from the remainder of
20 the device to facilitate the use of alternative storage means in an interchangeable manner.

38. A device according to claim 13 wherein the means for supplying electrical power comprises a connector for coupling to an external
25 power source.

39. A device according to claim 13 wherein the housing includes a cabinet lock and tamper-resistant fasteners for preventing

unauthorized access to the containers and mechanisms interior of said housing.

40. A device according to claim 13 wherein said dispensing means is driven manually.

5 41. A device according to claim 13 wherein said dispensing means is driven primarily by means of power not supplied by a user.

 42. A dispensing system comprising:
 one or more field units, each field unit
10 including

 storage means for storing a plurality of individual containers;

 dispensing means for dispensing one container at a time from said storage means, each
15 container being dispensed by executing an individual dispensing operation;

 sequencing means for maintaining a predetermined order among the individual containers so that the individual containers are
20 dispensed in said predetermined order by said dispensing means, said sequencing means also including means for providing a predetermined spacing relationship between containers so that they can be engaged by the dispensing means;

25 electronic memory means for storing data, including instructions for operating the device;

 electronic time keeping means for providing time information;

30 electronic logic means for interpreting and executing said instructions;

means for communicating data to/from
said field unit;

means for supplying electrical power
to the time keeping means, logic means, memory and
5 communicating means; and

a housing containing said storage
means, dispensing means, sequencing means, memory
means, time keeping means, logic means,
communicating means and power supplying means; and

10 a base unit for transferring said data
to/from said field unit and/or preparing a report
of said data sent or received.

43. A system according to claim 42
wherein said field unit further includes means for
15 sensing and signalling to said logic means, each
completed dispensing operation of said dispensing
means.

44. A system according to claim 42
wherein said storage means includes a
20 substantially 'U' shaped partition defining a
passageway.

45. A system according to claim 42
wherein said storage means includes a passageway
having a width less than two container diameters.

25 46. A system according to claim 42
wherein said dispensing means comprises: an
ejector element mounted for rotation about a
longitudinal axis thereof and having container
conforming depressions around its periphery, said
30 depressions being shaped so as to engage and
convey individual containers arranged in said

storage means in said predetermined order; said
ejector element, when rotated through a
predetermined angle, causing one container to be
dispensed and the next container in sequence to be
5 moved into a position ready to be dispensed upon
the next ejector rotation.

47. A system according to claim 46
wherein said ejector element has substantially a
cross-sectional form of a square with semicircular
10 depressions in each side of the square for
engaging cylindrical-shaped containers.

48. A system according to claim 46
wherein said dispensing means further includes
reverse rotation preventing means for preventing
15 potentially harmful rotation of the ejector
element in the direction opposite that used to
dispense a container.

49. A system according to claim 48
wherein operation of said reverse rotation
20 preventing means, through a common mechanism
simultaneously produces a completed dispensing
operation signal.

50. A system according to claim 42
wherein said dispensing means includes a stop
25 arrangement, operable in set and reset positions,
that prevents, after each container is dispensed,
further dispensing action until the stop mechanism
is reset.

51. A system according to claim 50 further including means for resetting said stop mechanism by means of linkages accessible to a user.

5 52. A system according to claim 50 further including a solenoid and linkages for resetting said stop mechanism under control of said electronic logic means in accordance with said stored instructions thereby controlling the
10 operator's ability to dispense containers, according to said instructions.

53. A system according to claim 52 wherein a power source separate from said power supplying means is used for powering the solenoid.

15 54. A system according to claim 50 wherein the stop mechanism includes latching means for preventing movement of the stop mechanism out of its set or reset positions except as provided by said instructions.

20 55. A system according to claim 42 further comprising audible indicating means, controlled by said logic means, for alerting a user as to when a container should be dispensed according to a predetermined schedule defined by
25 said instructions.

56. A system according to claim 55 wherein said audible indicating means comprises a piezoelectric alarm.

57. A system according to claim 42 further comprising visual indicating means, controlled by said logic means, for prompting a user as to when a container should be dispensed according to a predetermined schedule defined by said instructions.

58. A system according to claim 57 wherein said visual indicating means comprises a liquid crystal display.

59. A system according to claim 42 wherein said sequencing means comprises a thin, flexible strip with regularly spaced sleeves for holding individual containers, one in each sleeve, in a predetermined order.

60. A system according to claim 59 wherein said thin, flexible strip is adapted so that after it is loaded with containers, it can be folded into said storage means back and forth across a passageway thereof so that the containers may be dispensed by the dispensing means in said predetermined order.

61. A system according to claim 43 further comprising second memory means for storing data including times of actual dispensing of containers.

62. A system according to claim 61 wherein said communicating means transmits said data from the device to said base unit.

63. A system according to claim 62
wherein said base unit comprises a general purpose
computer, specially programmed to carry out its
functions of debriefing said field unit of said
5 data including times of actual dispensing and
preparing a report of actual dispensing data.

64. A system according to claim 42
wherein said communicating means receives from the
base unit all or part of said instructions for
10 storage in said memory means,

65. A system according to claim 64
wherein said base unit comprises a general purpose
computer, programmed to carry out its functions of
transmitting all or part of said instructions to
15 said field unit before the field unit is used for
dispensing.

66. A system according to claim 43
wherein said sensing and signalling means
comprises electrical switches activated by
20 actuators following cams of the dispensing means.

67. A system according to claim 42
wherein the means for supplying electrical power
comprises a battery.

68. A system according to claim 42
25 wherein the means for supplying electrical power
comprises a connector for coupling to an external
power source.

69. A system according to claim 42 wherein said housing includes a cabinet lock and tamper-resistant fasteners for preventing unauthorized access to said containers and mechanisms interior of said housing.

70. A device according to claim 42 wherein said dispensing means is driven manually.

71. A device according to claim 42 wherein said dispensing means is driven primarily by power not supplied by a user.

72. A system according to claim 42 wherein the storage means is in a portion of the housing that is separable from the remainder of the device, such that alternative storage means, each holding containers of different capacity, may be used interchangeably.

73. A medication dispensing device, comprising:

medication storage means for storing a plurality of individual medication containers arranged in a predetermined sequence;

means for storing a drug therapy schedule defining predetermined times and conditions under which medication containers should be dispensed from said medication storage means;

dispensing means for dispensing from said medication storage means, in response to a patient manipulation thereof at one of said predetermined times of said drug therapy schedule, a medication container;

means for storing information as to the times of actual dispensing of containers for reporting patient compliance with the drug therapy schedule.

5 74. A device according to claim 73 further including indicator means for indicating to a patient when he should dispense a medication container and administer to himself a medication contained therein.

10 75. A device according to claim 73 wherein said dispensing means further includes means for preventing the dispensing of a container at times other than said predetermined times of said drug therapy schedule.

15 76. A device according to claim 74 wherein said indicating means comprises audible alarm means for alerting the patient when one of said predetermined times is near or has passed without a dispensing of a medication container.

20 77. A device according to claim 76 wherein said audible alarm means comprises a piezoelectric alarm.

25 78. A device according to claim 73 wherein said therapy schedule further includes instructions for changing the drug therapy schedule in response to a failure of the patient to dispense a medication container at one or more of said predetermined times.

79. A device according to claim 73 further comprising means for transmitting information stored in said storing means.

80. A device according to claim 73
5 further comprising means for communicating the drug therapy schedule to said drug schedule storage means.

81. A device according to claim 73 wherein said medication containers are vials
10 attached to a belt.

82. A device according to claim 74 wherein said indicator means comprises a digital display for indicating when a next dosage is due to be dispensed according to said schedule.

83. A device according to claim 75
15 wherein said dispensing means comprises a locking arrangement for blocking free access to said containers; a solenoid for unlocking said locking arrangement so that the dispensing means can be
20 manually manipulated at said predetermined times; and microprocessor means for controlling said solenoid according to said schedule.

84. A device according to claim 73 wherein said dispensing means comprises a sprocket
25 mounted for rotation about a longitudinal axis thereof and having grooves therein for accommodating and conveying said containers.

85. A device according to claim 84 further comprising electrical switches coupled so

as to be actuated by rotation of said sprocket,
said switches providing said information as to the
times of actual dispensing of containers.

86. A medication dispensing system,
5 comprising:

a base unit for defining a drug
dispensing schedule according to which a field
unit is to dispense drugs, debriefing the field
unit after it has dispensed drugs, and providing a
10 report on the information debriefed; and

a field unit including means for
receiving drugs to be dispensed, means for
receiving and storing the dispensing schedule from
said base unit, means for permitting drugs to be
15 dispensed according to said schedule, means for
recording actual times of drug dispensing, and
means for transmitting the recorded information to
said base unit.

87. A system according to claim 86
20 further comprising additional field units, each of
which can be operated with said base unit.

88. A system according to claim 86
wherein said base unit comprises a computer
programmed to carry out its defining, debriefing
25 and reporting functions.

89. A system according to claim 88
wherein said field unit comprises:

medication storage means for storing a
plurality of individual medication containers
30 arranged in a predetermined sequence;

means for storing said dispensing
schedule;

indicator means for indicating to a user
when he should dispense a medication container and
5 administer to himself a medication contained
therein; and

dispensing means for dispensing from said
medication storage means, in response to a patient
manipulation thereof at one of said predetermined
10 times of said schedule, a medication container.

90. A system according to claim 89
wherein said dispensing means further comprises
means for preventing the dispensing of a container
at times other than said predetermined times of
15 said schedule.

91. A system according to claim 89
wherein said field unit further comprises means
for storing information as to the times of actual
dispensing of containers for reporting compliance
20 with said schedule.

92. A system according to claim 89
wherein said indicator means includes audible
alarm means for alerting the user when a
dispensing time is near or has passed without a
25 dispensing of a medication container.

93. A system according to claim 92
wherein said alarm means comprises a piezoelectric
alarm.

94. A system according to claim 89
30 wherein said field unit further includes means for

changing the dispensing schedule in response to a failure of the patient to dispense a medication container at a dispensing time.

95. A system according to claim 89
5 wherein said medication containers are vials attached to a belt.

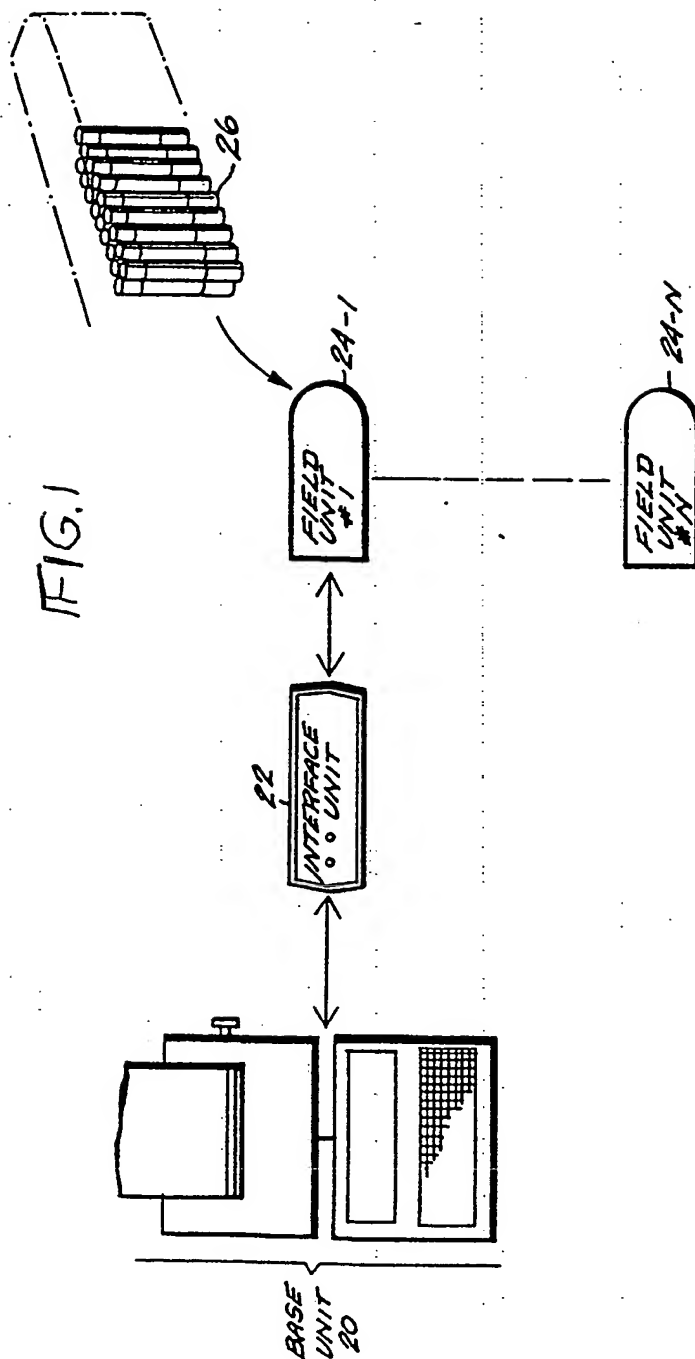
96. A system according to claim 89
wherein said indicator means comprises a digital display for indicating when a next dosage is due
10 to be dispensed according to said schedule.

97. A system according to claim 90
wherein said dispensing means comprises a locking arrangement for blocking free access to said containers; a solenoid for unlocking said locking
15 arrangement so that the dispensing means can be manually manipulated at said predetermined times; and microprocessor means for controlling said solenoid according to said schedule.

98. A system according to claim 89
20 wherein said dispensing means comprises a sprocket mounted for rotation about a longitudinal axis thereof and having grooves therein for accommodating and conveying said containers.

99. A system according to claim 98
25 further comprising electrical switches coupled so as to be actuated by rotation of said sprocket, said switches providing said information as to the times of actual dispensing of containers.

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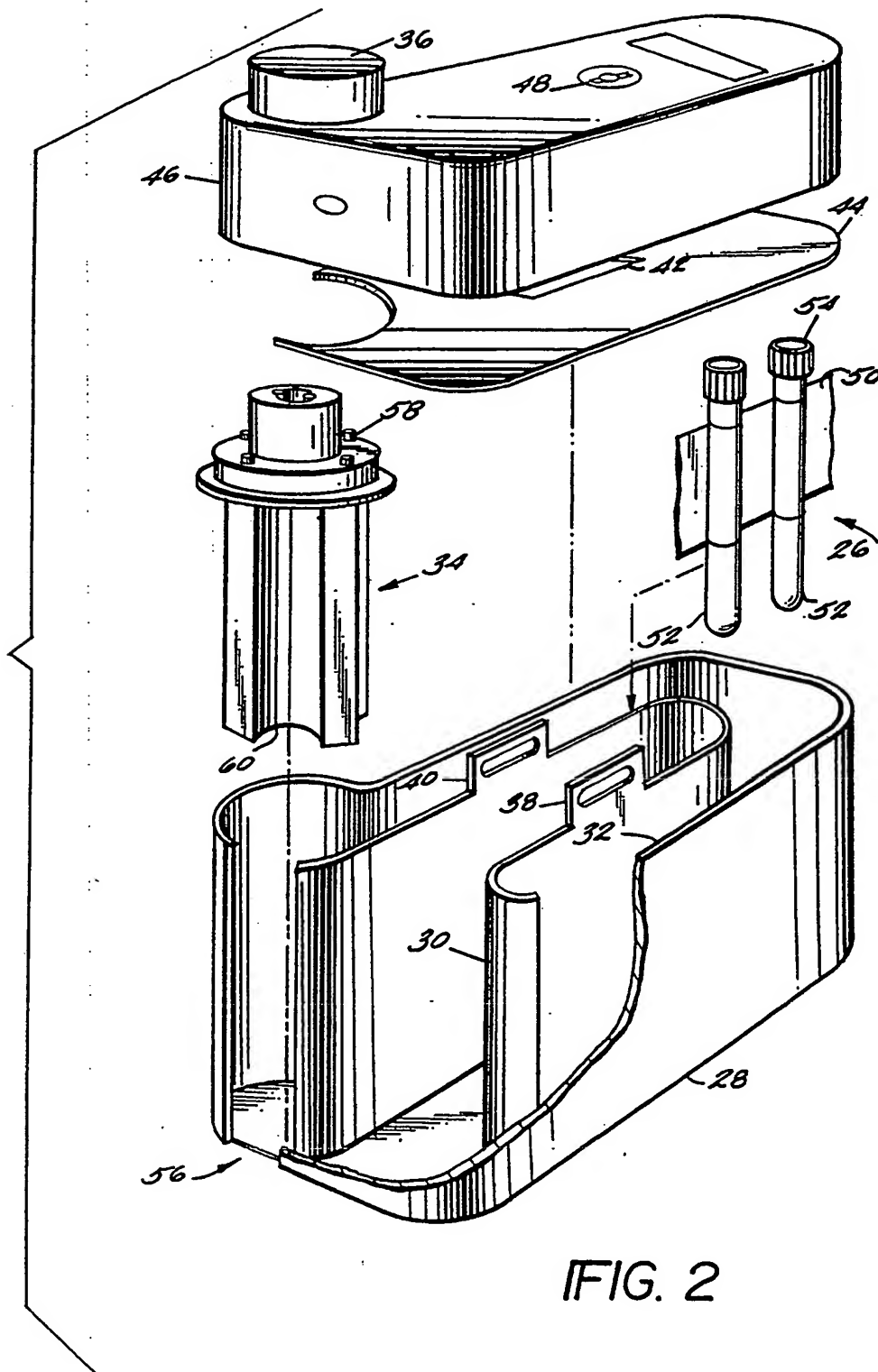


FIG. 2

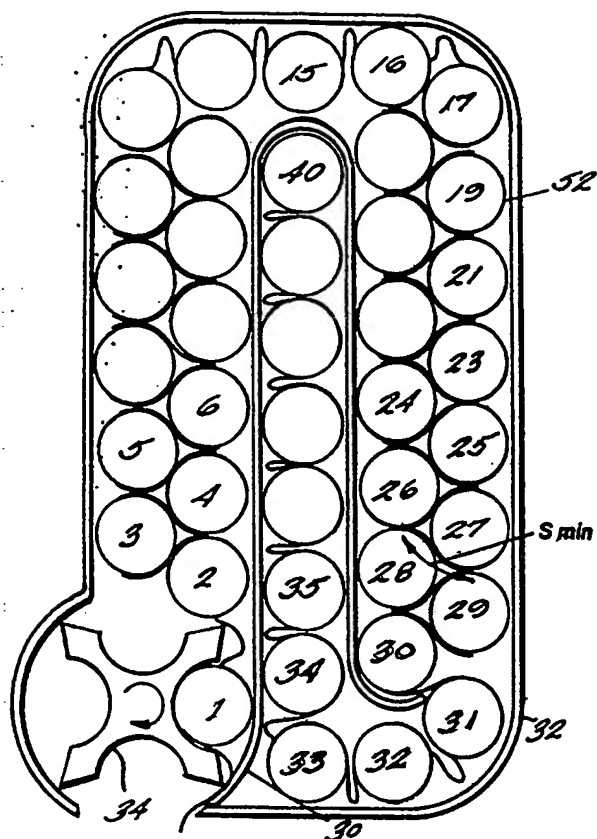


FIG. 4

FIG. 3

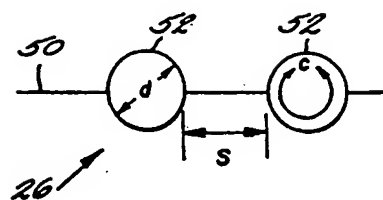


FIG. 5

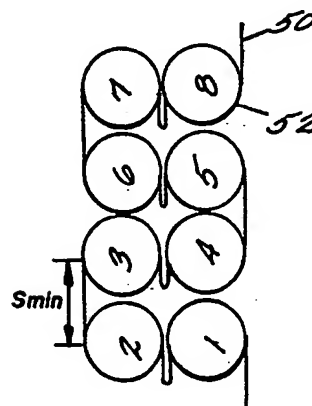


FIG. 6

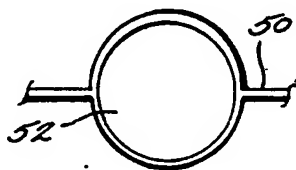


FIG. 7

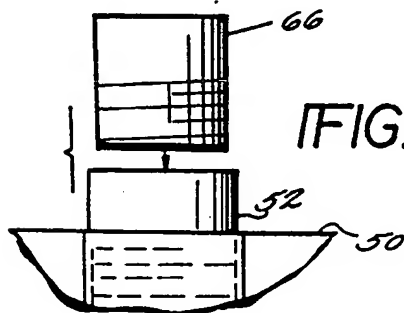
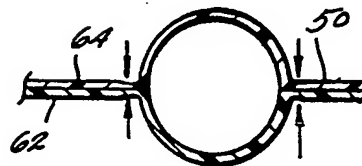
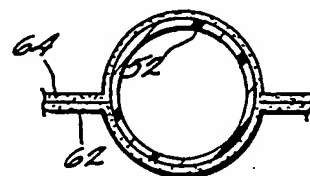


FIG. 9

FIG. 8



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FIG. 10

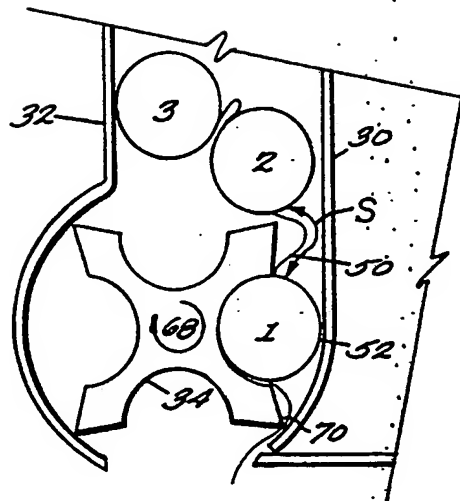


FIG. 11

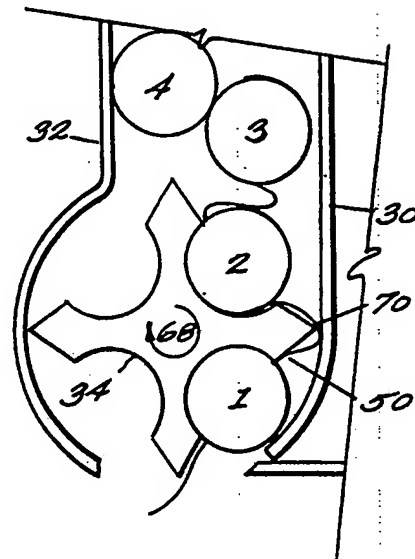
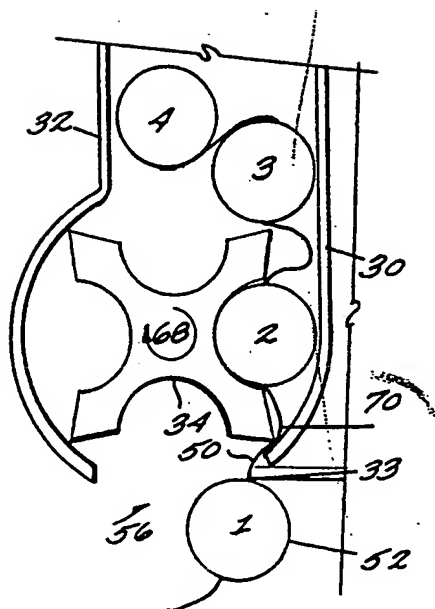


FIG. 12



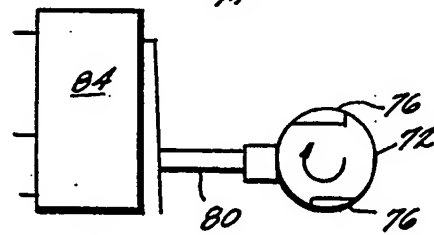
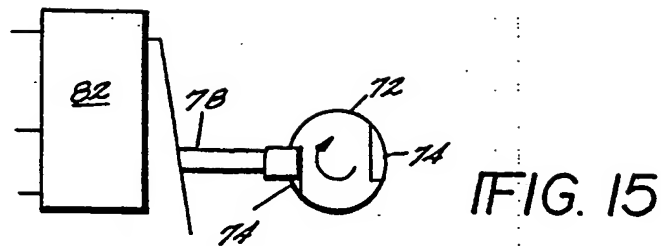


FIG. 13

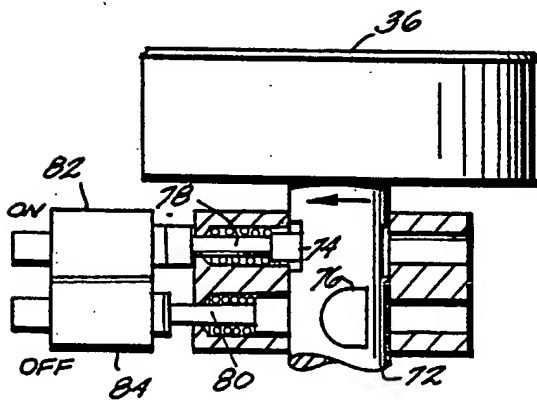


FIG. 14

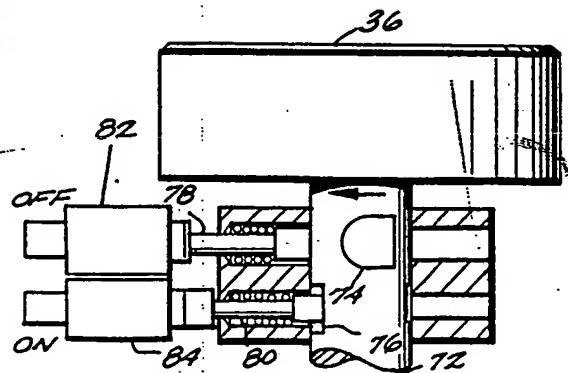


FIG. 17

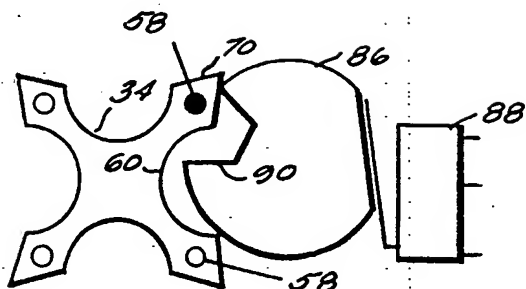


FIG. 18

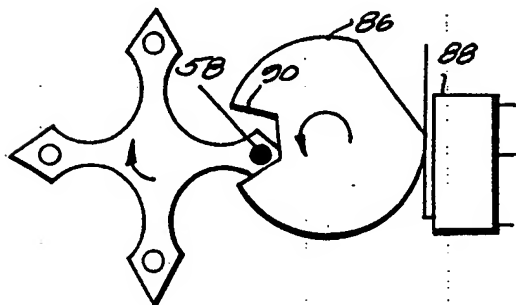


FIG. 19

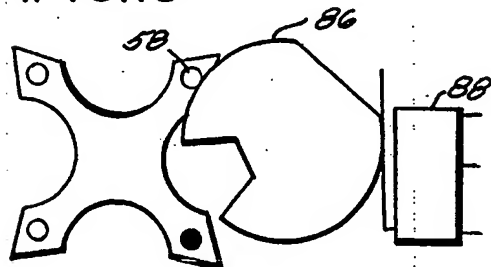


FIG. 20

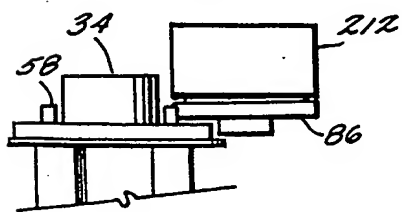


FIG. 21

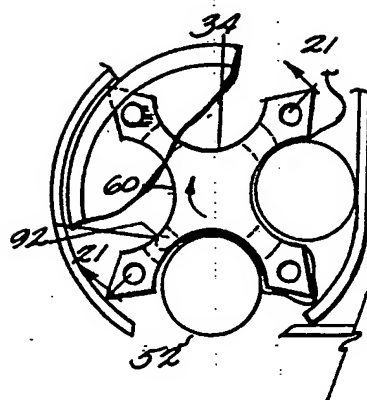
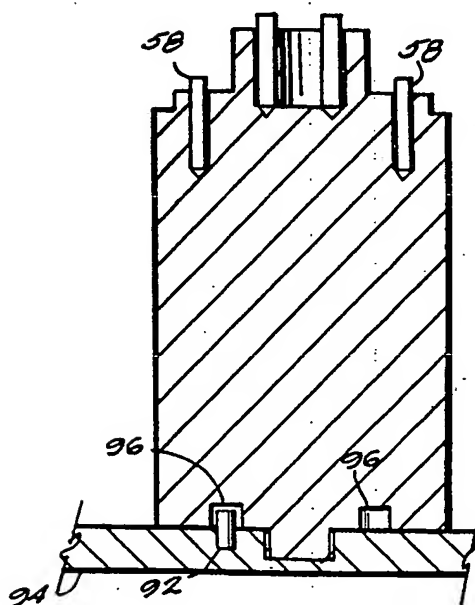


FIG. 22



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FIG. 24

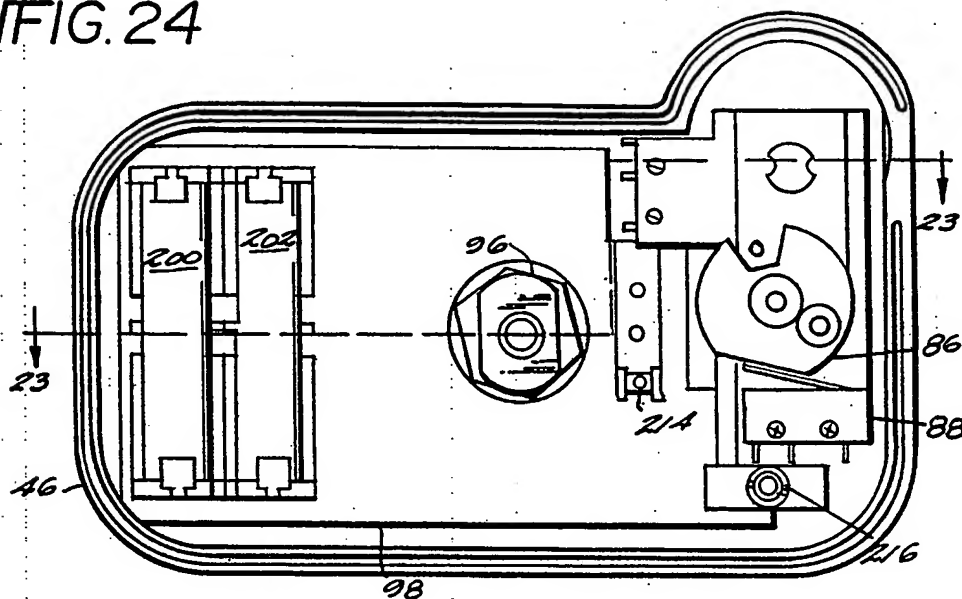


FIG. 23

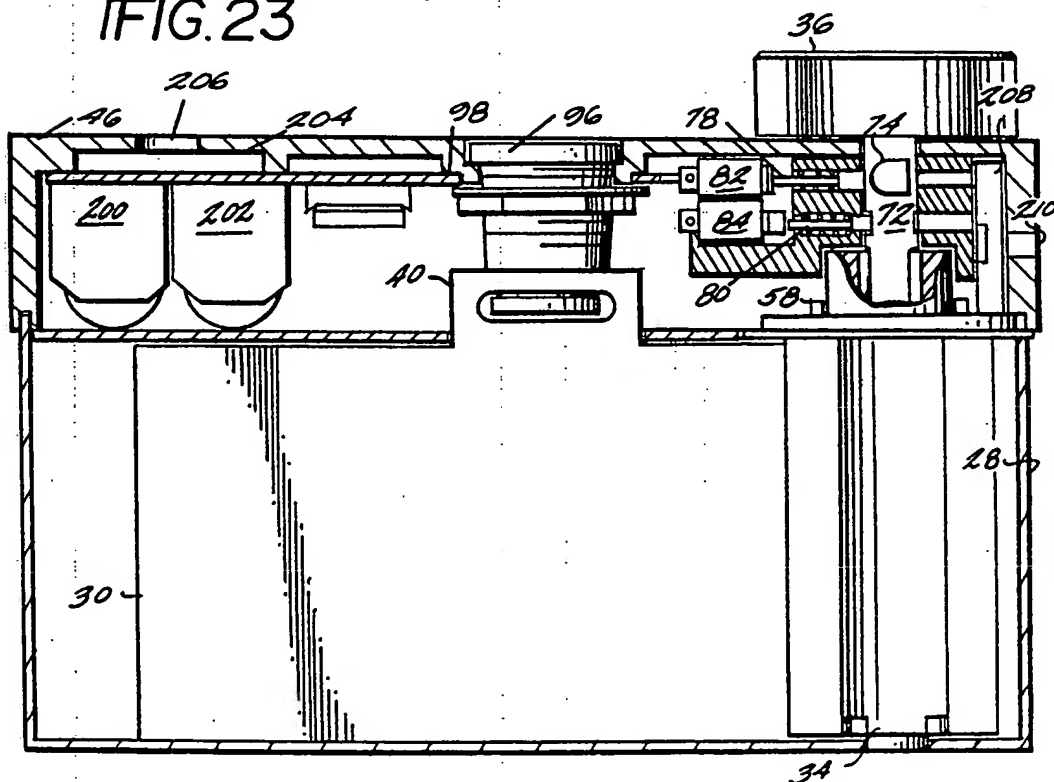
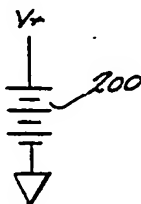
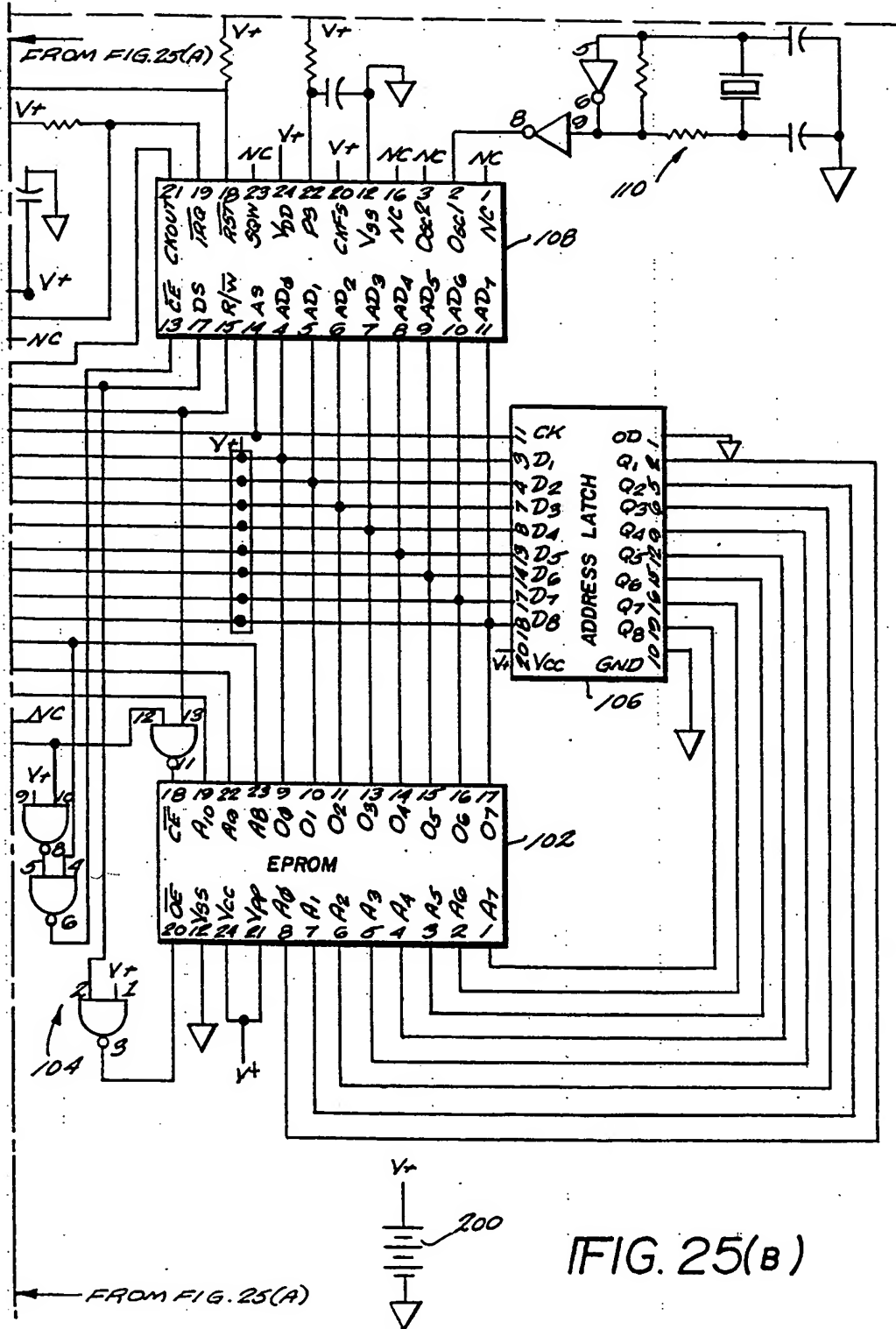
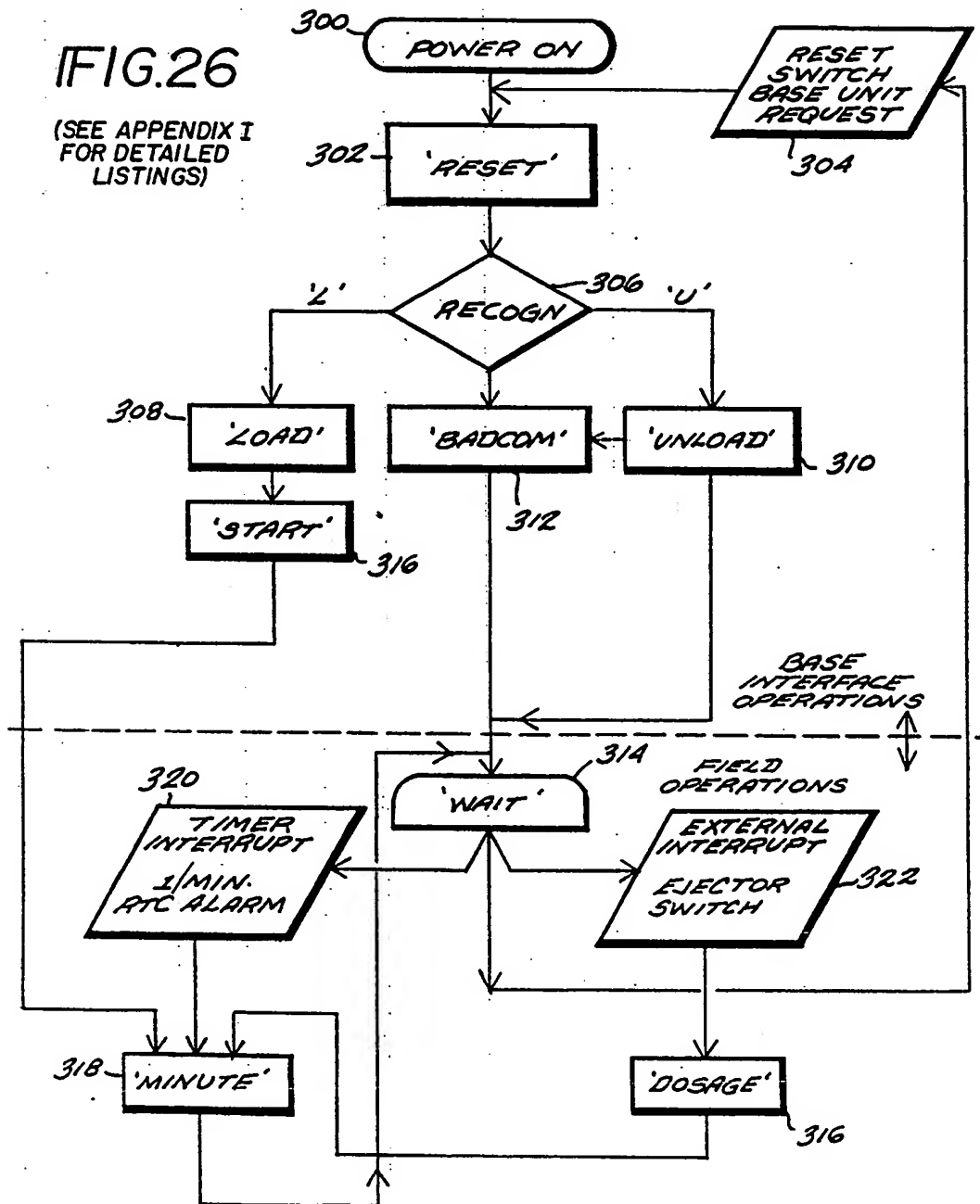


FIG.
25 (A)



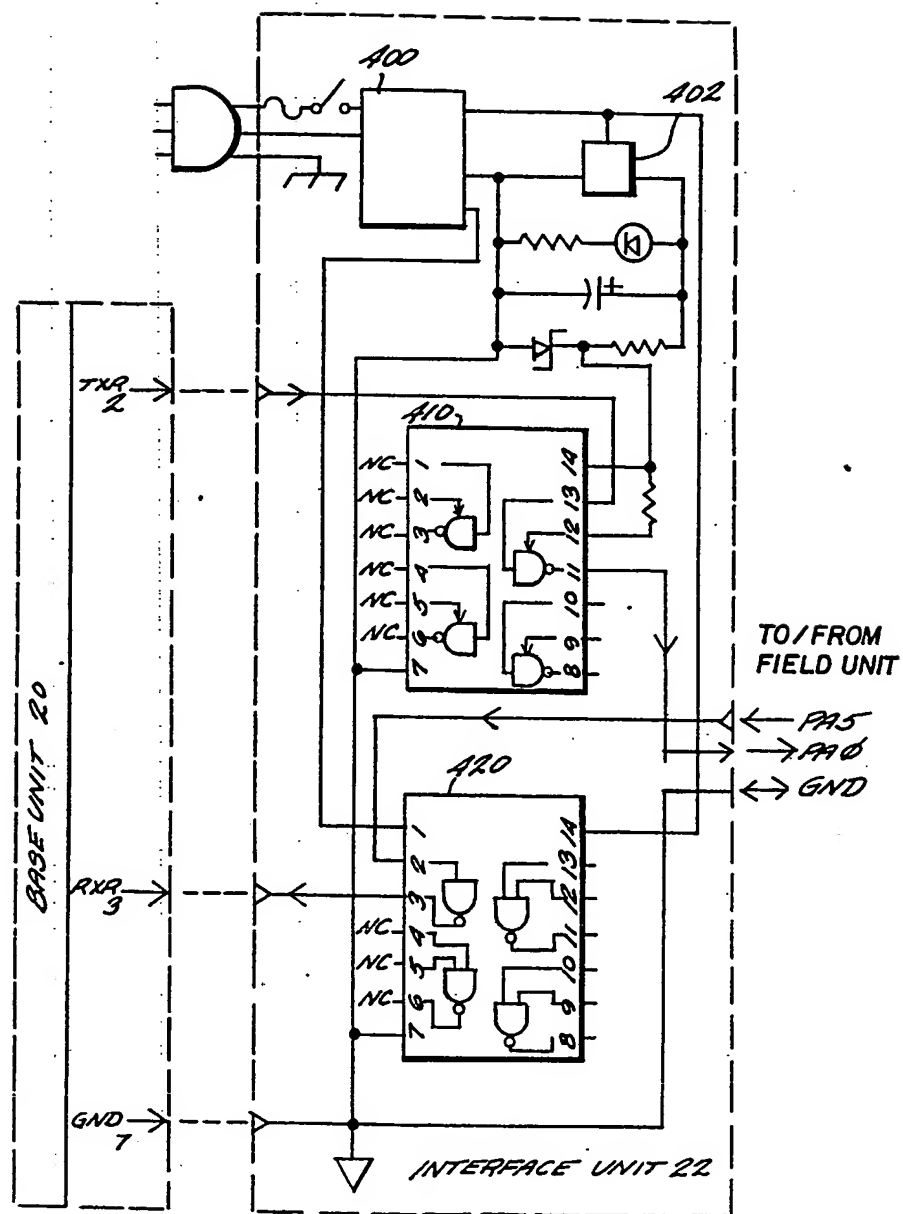
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FIG. 26

(SEE APPENDIX I
FOR DETAILED
LISTINGS)

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FIG. 27



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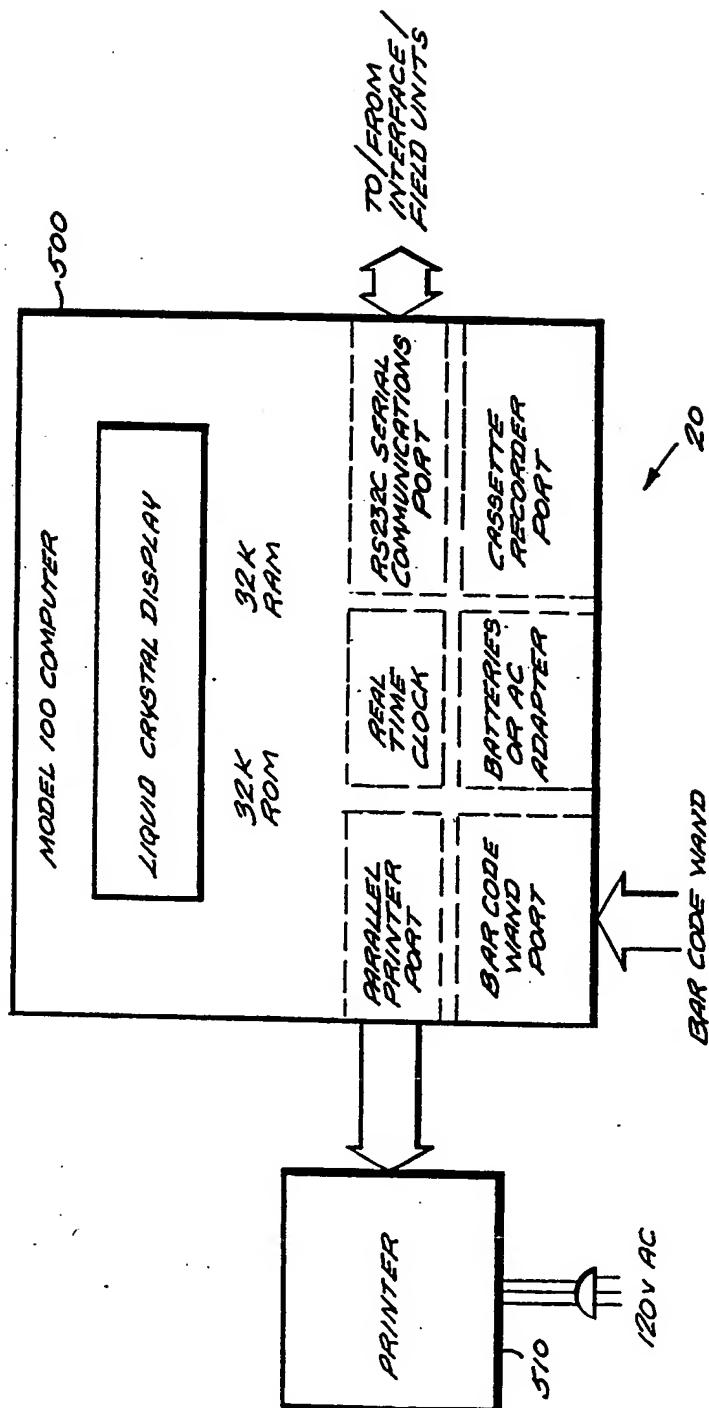
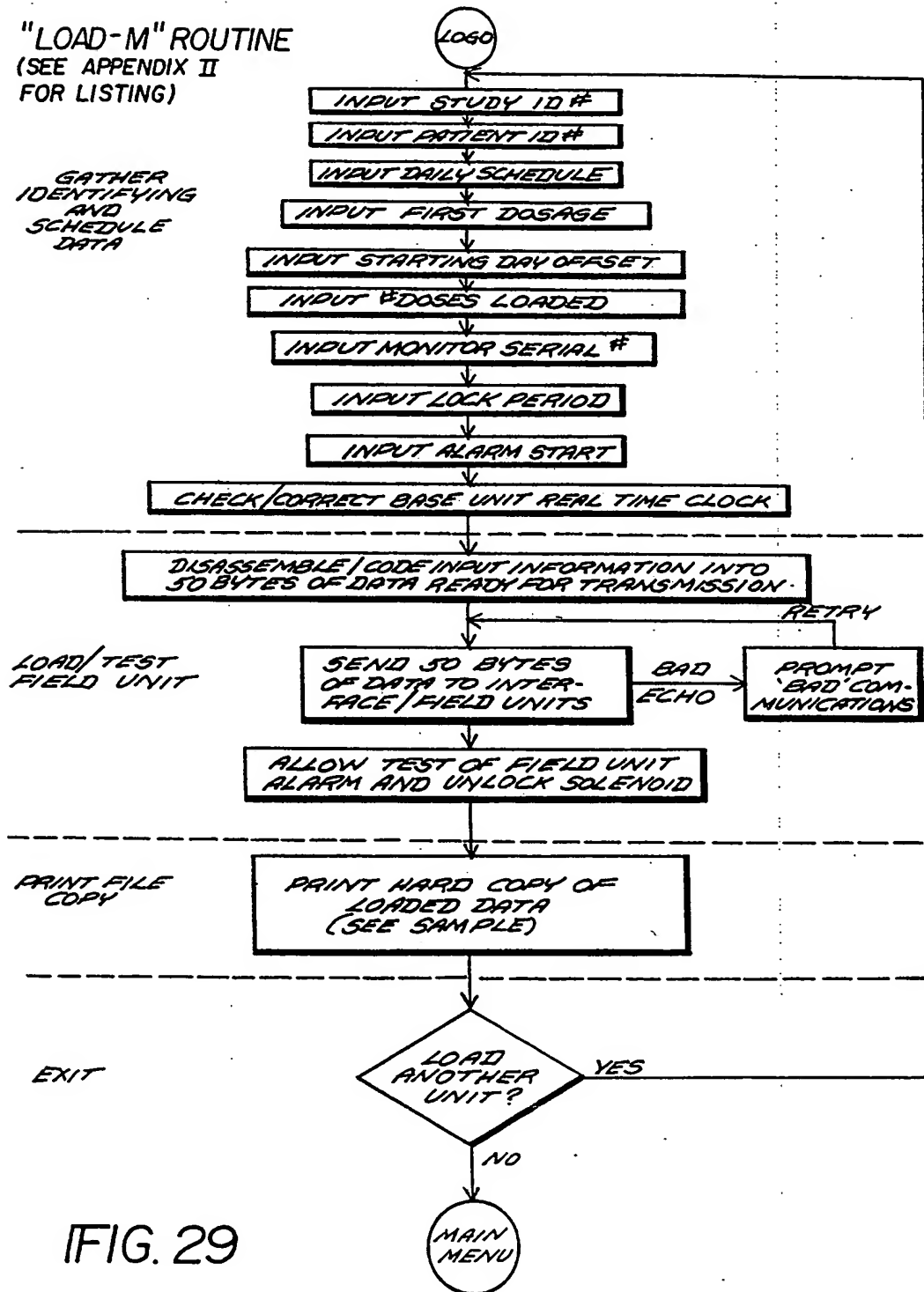


FIG. 28

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"LOAD-M" ROUTINE
(SEE APPENDIX II
FOR LISTING)

GATHER
IDENTIFYING
AND
SCHEDULE
DATA



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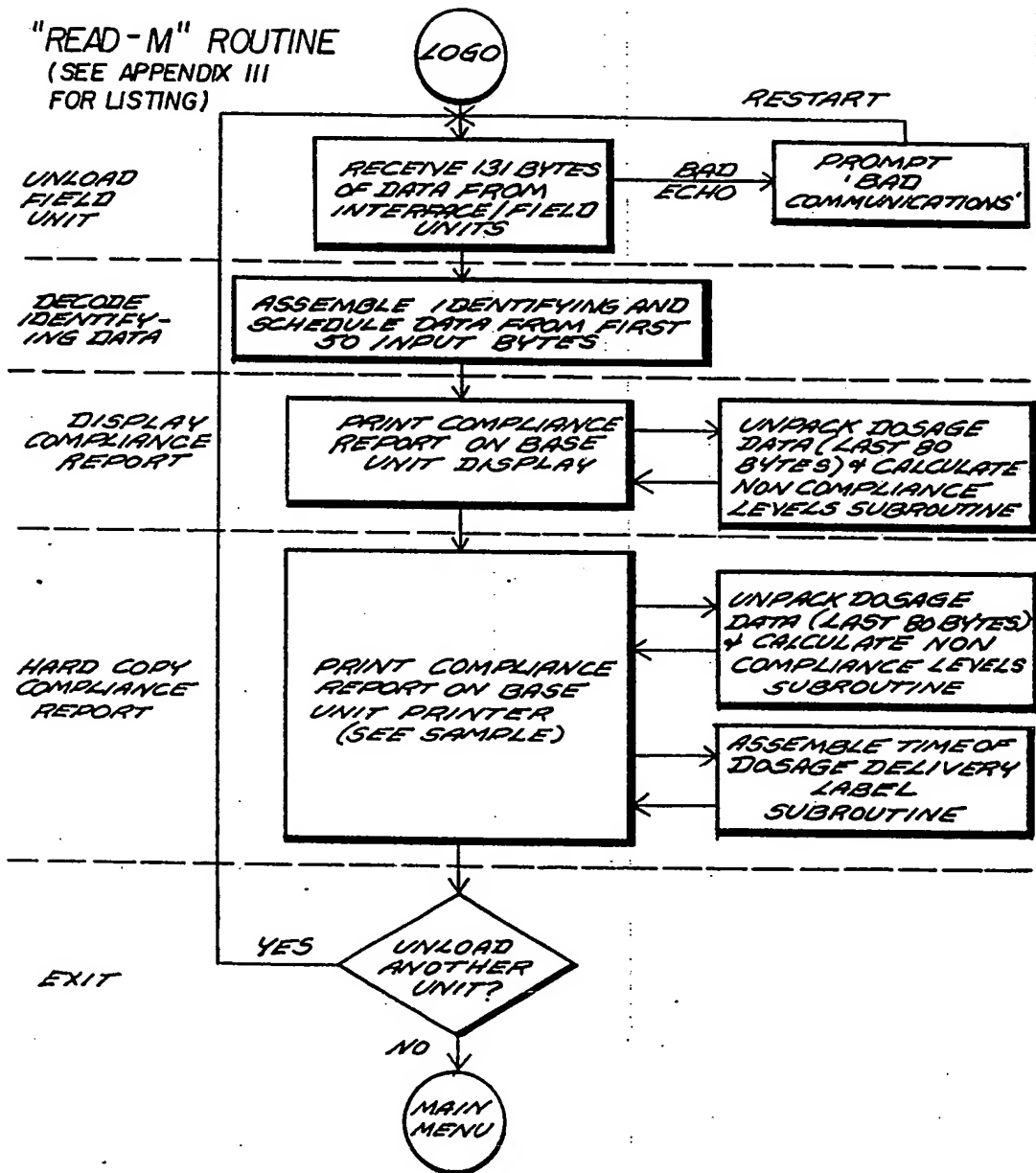


FIG. 30

INTERNATIONAL SEARCH REPORT

International Application No **PCT/US86/00711**

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all)

According to International Patent Classification (IPC) or to both National Classification and IPC
Int. Cl. 4 B65D 83/04
U.S. Cl. 221/3

II. FIELDS SEARCHED

Minimum Documentation Searched *	
Classification System	Classification Symbols
U.S.	186/55 206/531, 532, 534 221/3, 5, 9, 13, 15, 25, 30-31, 71-74, 265-266 340/309.3, 309.4, 309.15 364/479

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched *

III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴

Category *	Citation of Document, ¹⁵ with Indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁶
Y	US, A, 3,917,045, (Williams), 04 November 1975.	1-5, 9-20, 26-49, 84-89, 92-96, 98.
Y, P	US, A, 4,572,403, (Benaroya), 25 February 1986.	10-20, 26- 49, 55-82, 84-89, 92- 96, 98
Y	US, A, 2,941,643, (Donnelly), 21 June 1960.	1-5, 9, 17- 20, 35, 46- 49, 66, 73, 98
Y	US, A, 3,984,030, (Morini), 05 October 1976.	31, 60
Y	US, A, 3,985,264, (Shaw), 12 October 1976.	32-33, 61- 63, 73-82, 86-89, 92- 93, 95-96

* Special categories of cited documents: ¹⁴

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"A" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search *

26 June 1986

International Searching Authority ¹

ISA/US

Date of Mailing of this International Search Report *

02 JUL 1986

Signature of Authorized Officer ¹⁸

Michael S. Huppert 6-30-86
Michael S. Huppert

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, ¹ with indication, where appropriate, of the relevant passages ²	Relevant to Claim No ³
Y	US, A, 1,845,879, (Knee), 16, February 1932	40, 70
Y	US, A, 3,815,780, (Bauer), 11 June 1974	94
A,	US, A, 772,503, (Dodson), 18 October 1904	
A	US, A, 3,369,697, (Glucksman) 20, February 1968	
A	US, A, 3,968,900, (Stambuk), 13 July 1976	

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹⁰

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers _____, because they relate to subject matter ¹² not required to be searched by this Authority, namely:
2. ☐ Claim numbers _____, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out ¹³, specifically:

VI ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ¹¹

This International Searching Authority found multiple inventions in this international application as follows:

The lack of unity of invention holding, set forth on PCT/ISA/206 is hereby withdrawn.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.